

# **Exhibit A**

*Complaint as filed with Exhibits A-D*

GALLAGHER LAW, P.C.  
BY: JOAN D. GALLAGHER, ESQUIRE  
ATTY I.D.# 84081  
1600 MARKET STREET, SUITE 1320  
PHILADELPHIA, PENNSYLVANIA 19103  
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[joanie@gallagher-law.com](mailto:joanie@gallagher-law.com)  
MESSA & ASSOCIATES, P.C.  
BY: THOMAS N. SWEENEY, ESQUIRE  
ATTY I.D.#84192  
123 SOUTH 22<sup>ND</sup> STREET  
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[tsweeney@messalaw.com](mailto:tsweeney@messalaw.com)

Attorneys for Plaintiffs

Filed and Attested by the  
Office of Judicial Records  
24 OCT 2018 12:05 pm



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PETER HUMPHREY, YU YINGZENG	:	COURT OF COMMON PLEAS
AND CHINAWHYS COMPANY LTD	:	PHILADELPHIA COUNTY
Buttermere, Horley Lodge Lane,	:	
Salfords, Redhill, RH1 5EA	:	
United Kingdom	:	
v.	:	
GLAXOSMITHKLINE PLC	:	
1 Franklin Plaza	:	
200 N. 16 <sup>th</sup> Street	:	
Philadelphia, PA 19102	:	
and	:	
GLAXOSMITHKLINE LLC	:	
Philadelphia Navy Yard	:	
5 Crescent Drive	:	OCTOBER TERM, 2018
Philadelphia, PA 19112	:	NO.

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### **CIVIL ACTION**

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this Complaint & Notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the Court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

PHILADELPHIA BAR ASSOCIATION  
Lawyer Referral & Information Service  
One Reading Center  
Philadelphia, PA 19107  
(215) 238-1701

### **AVISO**

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de s persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder u otros derechos importantes para usted.

LLEVE ESTAS DEMANDA A UN ABOGADO INMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO. VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVAERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

ASOCIACION DE LICENCIADOS DE FILADELFA  
Servicio De Referencia E Informacion Legal  
One Reading Center  
Filadelfia, PA 19107  
(215) 238-1701

Case ID: 181003237

GALLAGHER LAW, P.C.  
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Attorneys for Plaintiffs

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PETER HUMPHREY, YU YINGZENG	:	COURT OF COMMON PLEAS
AND CHINAWHYS COMPANY LTD	:	PHILADELPHIA COUNTY
Buttermere, Horley Lodge Lane,	:	
Salfords, Redhill, RH1 5EA	:	
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Philadelphia, PA 19112	:	NO.

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**COMPLAINT FILED PURSUANT TO TITLE 42, PENNSYLVANIA CODE, SECTION 5103 AND TITLE 28, UNITED STATES CODE, SECTION 1367(d)**

Plaintiffs Peter Humphrey, Yu Yingzeng, and ChinaWhys Company Ltd. hereby submit the attached Complaint against Defendants GlaxoSmithKline PLC and GlaxoSmithKline LLC pursuant to Title 42, Pennsylvania Code, Section 5103 (herein “PA Section 5103”) and Title 28, United States Code, Section 1367(d) (herein “U.S.C. Section 1367(d)).

PA Section 5103 provides that “[w]here a matter is filed in any United States court for a district embracing any part of this Commonwealth and the matter is dismissed by the United States court for lack of jurisdiction, any litigant in the matter filed may transfer the matter to a court or magisterial district of this Commonwealth by complying with the transfer provisions set forth in paragraph (2).” 42 Pa.C.S. § 5103(b)(1). Paragraph (2) states: “[e]xcept as otherwise prescribed by general rules, or by order of the United States court, such transfer may be effected by filing a certified transcript of the final judgment of the United States court and the related pleadings in a court or magisterial district of this Commonwealth.” 42 Pa.C.S. § 5103(b)(2). To proceed under PA Section 5103, “a litigant, upon having his case dismissed in federal court for lack of jurisdiction, must promptly file a certified transcript of the final judgment of the federal court and, at the same time, a certified transcript of the pleadings from the federal action. The litigant shall not file new pleadings in state court.” *Williams v. F.L. Smithe Mach. Co., Inc.*, 395 Pa. Super. 511, 516-17 (1990).

On or about November 15, 2016, Plaintiffs filed the Complaint attached hereto as Exhibit A in the United States District Court for the Eastern District of Pennsylvania. Thereafter, Defendants moved to dismiss the Complaint. The District Court granted Defendants’ motion on or about September 29, 2017 for lack of jurisdiction. [A certified copy of the Order dismissing the Complaint is attached as Exhibit B.] Plaintiffs appealed that decision to the United States Court of Appeals for the Third Circuit on or about October 16, 2017. The Third Circuit affirmed the decision of the District Court dismissing the Complaint and issued its mandate on October 18, 2018. [A certified copy of the Judgment is attached hereto as Exhibit C] A certified transcript of the docket as well as related pleadings from those federal proceedings are attached hereto as Exhibit D.

Plaintiffs hereby file the Complaint pursuant to PA Section 5103. The Complaint is also filed in a timely manner pursuant to U.S.C. Section 1367(d)) which provides that “[t]he period of limitations for any claim asserted under subsection (a), and for any other claim in the same action that is voluntarily dismissed at the same time as or after the dismissal of the claim under subsection (a), shall be tolled while the claim is pending and for a period of 30 days after it is dismissed unless State law provides for a longer tolling period.” 28 U.S.C. 1367(d). Because of there was a dismissal based upon lack of jurisdiction, Plaintiff fulfills the requirements of PA Section 5103 and submits the attached Complaint in compliance with PA Section 5103.

**WHEREFORE,** Plaintiffs bring this action against Defendants to recover damages in a sum in excess of fifty thousand dollars (\$50,000), plus interest, costs, and delay damages under Rule 238, Pennsylvania Rules of Civil Procedure.

Dated: October 23, 2018

Respectfully Submitted,  
GALLAGHER LAW, P.C.

By: /s/ Joan D. Gallagher  
JOAN D. GALLAGHER, ESQUIRE  
ATTORNEY FOR PLAINTIFFS

MESSA & ASSOCIATES, P.C.

By: /s/ Thomas N. Sweeney  
THOMAS N. SWEENEY, ESQUIRE  
ATTORNEY FOR PLAINTIFFS

John T. Zach  
Boies, Schiller & Flexner LLP  
575 Lexington Avenue  
New York, New York, 10022  
(212) 446-2300  
[jzach@bsflp.com](mailto:jzach@bsflp.com)  
*To be admitted Pro Hac Vice*

**VERIFICATION**

JOAN D. GALLAGHER, ESQUIRE, certify that I am an attorney with Gallagher Law, P.C. counsel for Plaintiffs, and under the provisions of Pa. R.C.P. 1024(c), I hereby verify that the statements made in the foregoing pleading are true and correct to the best of my information and belief. I understand that false statements therein are made subject to the penalties of 18 Pa. C.S. § 4904 relating to unsworn falsification to authorities.

By: /s/ Joan D. Gallagher  
JOAN D. GALLAGHER, ESQUIRE  
ATTORNEY FOR PLAINTIFFS

Date: October 23, 2018

**VERIFICATION**

THOMAS N. SWEENEY, ESQUIRE, certify that I am an attorney with Messa & Associates, P.C. counsel for Plaintiffs, and under the provisions of Pa. R.C.P. 1024(c), I hereby verify that the statements made in the foregoing pleading are true and correct to the best of my information and belief. I understand that false statements therein are made subject to the penalties of 18 Pa. C.S. § 4904 relating to unsworn falsification to authorities.

By: /s/ Thomas N. Sweeney  
THOMAS N. SWEENEY, ESQUIRE  
ATTORNEY FOR PLAINTIFFS

Date: October 23, 2018

Filed and Attested by the  
Office of Judicial Records  
24 OCT 2018 12:05 pm  
A. SILIGRINI



# EXHIBIT - A

JS 44 (Rev. 07/16)

## CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS  
PETER HUMPHREY YU YINGZENG and CHINAWHY'S COMPANY LTD

DEFENDANTS  
GLAXOSMITHKLINE PLC and GLAXOSMITHKLINE LLC

(b) County of Residence of First Listed Plaintiff Surrey (United Kingdom)  
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant  
(IN U.S. PLAINTIFF CASES ONLY)

(c) Attorneys (Firm Name, Address, and Telephone Number)  
Joan D. Gallagher, Gallagher & Turchi, P.C., 1699 Market Street, Suite 1320  
Philadelphia, PA 19103 T: 215-963-1555 E: joanie@gallagher-law.com

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF  
THE TRACT OF LAND INVOLVED.

-AND-  
John T. Zach & Philip Bowman, Boies, Schiller & Flexner LLP  
575 Lexington Avenue, New York, NY 10022 T: 212-446-2366 E:  
jzach@bsflp.com, phowman@bsflp.com  
(MR. ZACH & MR. BOWMAN TO BE ADMITTED PRO HAC VICE)

Attorneys (If Known)

## II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff  
☐ 2 U.S. Government Defendant  
☒ 3 Federal Question  
(U.S. Government Not a Party)  
☐ 4 Diversity  
(Indicate Citizenship of Parties in Item III)

## III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                        | DEF                        |   | PTF                        | DEF                        |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State                   | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State                | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

## IV. NATURE OF SUIT (Place an "X" in One Box Only)

<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<b>PERSONAL INJURY</b> <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<b>FORFEITURE/PENALTY</b> <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other	<b>BANKRUPTCY</b> <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157	<b>OTHER STATUTES</b> <input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input checked="" type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	<b>PRISONER PETITIONS</b> <b>Habeas Corpus:</b> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <b>Other:</b> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act	<b>PROPRIETARY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark	<b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSD Title XVI <input type="checkbox"/> 865 RSI (405(g))
<b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609				<input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes	

## V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding  
☐ 2 Removed from State Court  
☐ 3 Remanded from Appellate Court  
☐ 4 Reinstated or Reopened  
☐ 5 Transferred from Another District (specify)  
☐ 6 Multidistrict Litigation - Transfer  
☐ 8 Multidistrict Litigation - Direct File

## VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

18 U.S.C. § 1964

Brief description of cause:

## VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

## VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE

11/15/2016

SIGNATURE OF ATTORNEY OF RECORD

*Joan D. Gallagher*

NOV 15 2016

FOR OFFICE USE ONLY

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: Horley Lodge Lane, Salfords, Redhill, RH1 5AE, United Kingdom

Address of Defendant: 5 Crescent Drive, Philadelphia, PA 19112

Place of Accident, Incident or Transaction: China

(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?  
(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a))

Yes ☐

No ☒

Does this case involve multidistrict litigation possibilities?

Yes ☐

No ☒

RELATED CASE, IF ANY:

Case Number: \_\_\_\_\_

Judge \_\_\_\_\_

Date Terminated: \_\_\_\_\_

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?  
Yes ☐ No ☒

CIVIL: (Place ☒ in ONE CATEGORY ONLY)

A. Federal Question Cases:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☒ All other Federal Question Cases  
(Please specify) RICO

B. Diversity Jurisdiction Cases:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify) \_\_\_\_\_
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases  
(Please specify) \_\_\_\_\_

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, Joan D. Gallagher, counsel of record do hereby certify:

- ☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;
- ☐ Relief other than monetary damages is sought.

DATE: 11/15/16

Attorney-at-Law

84081

Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 11/15/16

Attorney-at-Law

84081

Attorney I.D.#

NOV 15 2016

NIQA

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**CASE MANAGEMENT TRACK DESIGNATION FORM**

PETER HUMPHREY, YU YINGZENG, and :  
CHINAWHYS COMPANY LTD :  
v. :  
GLAXOSMITHKLINE PLC, and :  
GLAXOSMITHKLINE LLC :

CIVIL ACTION

NO. 16 5924

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

**SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:**

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)
- (f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

<u>November 15, 2016</u>	<u>Joan D. Gallagher</u>	<u>Plaintiffs</u>
<b>Date</b>	<b>Attorney-at-law</b>	<b>Attorney for</b>
<u>(215) 963-1555</u>	<u>(215) 963-9104</u>	<u>joanie@gallagher-law.com</u>
<b>Telephone</b>	<b>FAX Number</b>	<b>E-Mail Address</b>

(Civ. 660) 10/02

NOV 15 2016

Case ID: 181003237

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

---

PETER HUMPHREY,  
YU YINGZENG,  
CHINAWHYS COMPANY LTD

**COMPLAINT**

Plaintiffs,

v.

GLAXOSMITHKLINE PLC;  
GLAXOSMITHKLINE LLC

Case No.

Defendants.

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**COMPLAINT**

Plaintiffs Peter Humphrey, Yu Yingzeng, and ChinaWhys Company Ltd. allege the following against Defendants GlaxoSmithKline PLC and GlaxoSmithKline LLC, based upon personal knowledge when in regards to themselves and upon information and belief and the investigation of counsel as to all other matters:

**NATURE OF THE ACTION**

1. This action arises out of a wide-ranging conspiracy by Defendants, in which they conspired to increase drug sales worldwide through, among other schemes, improper payments to doctors and other health care providers, and then further conspired to cover up their illegal activities. Defendants' conspiracy has been the subject of civil and criminal investigations by U.S. and non-U.S. government entities that have already resulted in the payment of huge fines and settlements by Defendants. Plaintiffs became victims of Defendants' scheme when a whistleblower in China sought to expose the scheme, and Defendants approached Plaintiffs to investigate the whistleblower, telling Plaintiffs that the whistleblower's allegations were false

and that the whistleblower was engaged in extortion. In fact, Defendants knew that the whistleblower's allegations were true, and Defendants' true motive was to use Plaintiffs to discredit the whistleblower and cover up their illegal scheme. Plaintiffs' work for Defendants, conducted based on Defendants' false statements, led to Plaintiff Humphrey and Yu's arrest, conviction and imprisonment in China, and the destruction of their business.

2. As described in further detail herein, when a whistleblower threatened to expose Defendants' widespread scheme of bribery and corruption in China, Defendants were desperate to prevent the scheme from coming to light because they were already effectively on probation as a result of an earlier investigation by the U.S. Department of Justice that had resulted in \$3 billion in fines and penalties and mandated compliance changes. They therefore approached Plaintiffs to conduct an investigation that Defendants hoped would hide the truth and obstruct further investigation. Their objective in retaining Plaintiffs was to create a dossier on the whistleblower, a former employee named Vivian Shi, to frame her as a vindictive former employee with a grudge in order to cover up their conspiracy and obstruct an ongoing investigation into it. Defendants lied to Plaintiffs, telling them that Defendants had investigated the allegations and found them to be untrue, and that the whistleblower was vindictive and engaged in a smear campaign even though Defendants knew that the whistleblower's allegations were true.

3. In reliance on Defendants' lies, Plaintiffs embarked on an investigation of Shi focusing on her contacts and ability to effectuate a smear campaign. As Defendants did or should have expected, this put Plaintiffs on a collision course with Shi, who was innocent, and her powerful allies within the Chinese Communist Party. As the head of Defendants' China business who had orchestrated the cover-up told Humphrey after the house of cards had begun to collapse

and he was preparing to flee China himself: “Shi has read your report and she is coming after you.” Plaintiffs Humphrey and Yu were, predictably, arrested, convicted in a summary proceeding, and sent to Chinese prison, where they remained in harsh conditions for almost two years, denied fresh air and proper medical treatment, and unable to see their teenage son or communicate with the outside world. While in confinement, Humphrey developed prostate cancer, for which he did not receive proper treatment, with the result that it became life-threatening. In addition, Plaintiffs lost the entire value of their profitable China due diligence business.

4. After Plaintiffs Humphrey and Yu were arrested, Defendants’ scheme was uncovered and publicly revealed. However, Defendants continued to make false statements about the investigation that they hired Plaintiffs to conduct. These false statements frustrated efforts by the British Foreign Office to secure the release of Humphrey and Yu. Thus, not only did Defendants’ conduct cause the imprisonment of Humphrey and Yu, but it prolonged it.

5. Plaintiffs, though this action, seek damages for the loss of their business, including substantial revenues from the United States, and compensation for the physical and emotional harm caused to Humphrey and Yu by their arrest and imprisonment in China and for damage to their reputation.

### **PARTIES**

6. Plaintiff Peter Humphrey is a co-founder of the investigations company ChinaWhys Company Ltd. (“ChinaWhys”) and a leading anti-fraud professional. Humphrey and ChinaWhys specialized in assisting U.S. and European law firms and businesses investigate and address compliance issues pertaining to anti-bribery regulations, including those set forth in the Foreign Corrupt Practices Act (“FCPA”). In particular, ChinaWhys assisted firms that were

being investigated by regulators in the United States, including the United States Department of Justice (the “DOJ”) and the United States Securities and Exchange Commission (the “SEC”). Humphrey was highly accredited and respected in the field and oversaw the Association of Certified Fraud Examiners China Chapter, which provides anti-fraud training and raises awareness about fraud. Humphrey is a “person” as defined under 18 U.S.C. § 1961(3).

7. Plaintiff Yu Yingzeng, an American citizen, is a co-founder of ChinaWhys and a fraud-prevention and detection expert in China. She is married to Humphrey. Yu is a “person” as defined under 18 U.S.C. § 1961(3).

8. Plaintiff ChinaWhys Ltd., is a business founded by Peter Humphrey and Yu Yingzeng to facilitate transparency and ethical business through the provision of risk management advice and consulting services, primarily focused on the prevention and exposure of internal corruption and fraud within multinational companies, including exposure and prevention of corruption and fraud in the client’s operations as well as pre-transactional due diligence to prevent future fraud. ChinaWhys is a “person” as defined under 18 U.S.C. § 1961(3).

9. At the time of the events relevant to this case, the majority of ChinaWhys’s contracts were with companies based in the United States, including major U.S. law firms and corporations. Much of this business focused on FCPA investigations and other internal investigations. At all times relevant to this matter, ChinaWhys had numerous pending engagements and contracts with law firms and businesses in the United States. As a result of Defendants’ actions, ChinaWhys lost significant revenue in the United States, and the ChinaWhys brand, goodwill and other assets were lost.

10. Defendant GlaxoSmithKline plc. (“GSK plc”) is a global pharmaceutical company with headquarters in Brentford, England; Philadelphia, Pennsylvania; and Durham, North Carolina. GSK plc is a “person” as defined under 18 U.S.C. § 1961(3). At all relevant times, GSK plc had the right to and did exercise control over the actions of its wholly-owned subsidiary GlaxoSmithKline (China) Investment Co., Ltd. (GSKCI)

11. Defendant GlaxoSmithKline LLC (“GSK LLC”), a subsidiary of GlaxoSmithKline plc., has its principal place of business and address at 5 Crescent Drive, Philadelphia, Pennsylvania. GSK is a “person” as defined under 18 U.S.C. § 1961(3). Hereinafter, “GSK” will refer to both GSK plc and GSK LLC unless otherwise noted.

#### **JURISDICTION AND VENUE**

12. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1332(a) and (c) and 18 U.S.C. § 1964.

13. This Court has personal jurisdiction over the parties because Plaintiffs have consented to this Court’s jurisdiction, and Defendants maintain headquarters in Philadelphia, Pennsylvania.

14. Venue is proper in this District under 28 U.S.C. § 1391 because Defendants maintain headquarters in within the district. Further, venue is proper under 18 U.S.C. § 1965.

#### **FACTUAL ALLEGATIONS**

##### **GSK Pays 3 billion to Settle Claims Involving Improper Payments to Doctors.**

15. This case is set against the background of various investigations into GSK’s criminal and illegal activities around the world and the intense scrutiny GSK was under by both criminal and civil regulatory authorities in the United States. In 2012, GSK entered into a

settlement agreement with the DOJ pursuant to which GSK LLC pled guilty to three misdemeanor charges under the Food, Drug and Cosmetic Act, and agreed to pay \$3 billion in penalties and damages, the “[l]argest combined federal and state health care fraud recovery in a single global resolution in the history of the United States.” The settlement resolved a wide range of allegations from promotion of a “false and misleading medical journal article” regarding the drug Paxil to misleadingly representing the lipid profile of drug Avandia. The settlement also resolved allegations of a pattern of illicit and corrupt relationships between GSK employees and medical doctors who prescribe GSK drugs. Specifically, with respect to one drug, Wellbutrin, “GSK paid doctors to attend lavish meetings in places such as Jamaica and Bermuda during which GSK provided off-label information to encourage doctors to write Wellbutrin prescriptions for unapproved uses of the drug.”

16. The settlement also resolved allegations that “GSK paid kickbacks to doctors to induce them to prescribe Advair, Flovent, Imitrex, Lotronex, Paxil, Wellbutrin, and Valtrex and other drugs, critically undermining the doctors’ independent clinical judgment.”

17. To resolve criminal charges, GSK LLC entered guilty pleas predicated on illegal activities associated with the drugs Paxil, Wellbutrin, and Avandia, for: “distribution of a misbranded drug due to false and misleading labeling, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) & 352(a)”; “distribution of a misbranded drug due to inadequate directions for use, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) & 352(f)(1)”; and “failure to report data to the FDA, in violation of 21 U.S.C. §§ 331(e), 333(a)(1) & 355(k)(1).” In connection with these guilty pleas, GSK LLC agreed to pay \$1 billion in criminal penalties, “the second-largest penalty for a drug company in a single criminal plea.”

18. Under the overarching agreement, GSK LLC also assented to three civil settlements, regarding: “allegations relating to false claims to federal health care programs resulting from marketing and promotion practices, including off-label marketing”; “allegations that GSK promoted Avandia to physicians and other health care providers with false and misleading representations, causing false claims to be submitted to federal health care programs”; and “allegations that GSK reported false best prices to the Department of Health and Human Services and as a result underpaid quarterly rebates owed under the Medicaid Drug Rebate Program.” The civil settlement includes \$2 billion in damages, “the largest civil recovery from a drug company in a single global resolution.”

19. The settlement also addressed a number of whistleblower allegations filed as *qui tam* actions under the federal False Claims Act, 31 U.S.C. § 3730.

20. The settlement also included prospective measures including a robust set of restrictions and procedures “designed to ensure GSK’s future compliance with the law,” ranging from annual certification of “appropriate compliance measures” to a “five-year Corporate Integrity Agreement.” That agreement “requires enhanced accountability, increased transparency and wide-ranging monitoring activities conducted by both internal and independent external reviewers.”

21. Finally, the settlement provided an exception to non-prosecution for potential actions under the Foreign Corrupt Practices Act, 15 U.S.C. § 78dd-1, *et seq.* While the settlement agreement contained a non-prosecution provision with the “Criminal Division of the United States Department of Justice,” it contained a carve out for “any investigations of GSK that are or may be conducted in the future by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the sales

and marketing of GSK's products to foreign customers, which investigations are specifically excluded from the release."

22. There was an important reason that this carve-out was included in the agreement. In 2010, the DOJ and the SEC had already initiated an FCPA investigation into pharmaceutical sales practices by GSK in China and other foreign nations. As set forth below, those investigations would eventually uncover widespread corruption by GSK and others with whom it was conspiring to further the sales of its drugs in China and elsewhere in the world.

#### **GSK Engages in Widespread Bribery in China From at Least 2010**

23. It is now clear that, from at least 2010, GSK was participating in widespread bribery in China. For example, from between at least 2010 and June 2013, employees and agents of GSK and a China-based joint-venture engaged in various transactions and schemes to provide things of value to foreign officials, including healthcare professionals, in order to improperly influence those individuals and increase sales of GSK products in China.

24. This misconduct was facilitated in part by the use of collusive third parties that ostensibly provided legitimate travel and other services. The funds used for the improper inducements were frequently obtained under the guise of, and falsely recorded in GSK's books and records as, legitimate travel and entertainment expenses, marketing expenses, speaker payments, payments to medical associations, and promotion expenses. Throughout this period, GSK failed to devise and maintain a sufficient system of internal accounting controls and lacked an effective anticorruption compliance program.

25. Indeed, between 2010 and June 2013, GSK spent nearly RMB 1.4 billion (USD \$225 million) on planning and travel services. However, test sampling showed that approximately 44 percent of the sampled invoices were inflated, and approximately 12 percent

were for events that did not occur. This, along with other plain evidence of bribery, was identified by the SEC in its investigation of GSK. In addition, in or around this same time period, GSK set up a special “crisis management” team in order to bribe Chinese regulators with money and gifts. Among other things, a GSK executive attempted to bribe a Chinese investigator with an iPad and a lavish dinner. This, and other bribes, were all approved by Mark Reilly who headed up GSK’s Chinese operations.

**GSK Receives Anonymous Letters Alleging Widespread Corruption in China**

26. Given the criminal and civil settlement that GSK reached with the DOJ in 2012, it was under tremendous pressure to avoid future scandals. Any additional finding of corruption would put GSK at risk of—among other things—harsher sanctions in the United States, further reputational harm, and significant harm to GSK’s share price. Likewise, with U.S. regulators vowing to hold senior company officials accountable for corporate fraud, GSK’s management well understood that they faced potential personal sanctions should future GSK misconduct be unearthed.

27. In or about December 2011, a whistleblower who worked for GSK sent an email to the Chinese regulators describing widespread fraud and corruption within the company. Thereafter, approximately two dozen emails were sent over a 17-month period that provided further details of fraud and corruption.

28. In or about April 2012, senior executives at GSK learned that a whistleblower was sending evidence of the company’s criminal activity to the Chinese government. Thereafter, GSK worked to learn the identity of the whistleblower so that it could execute a plan to suppress the evidence of its illegal bribery activities. During this same time period, GSK was negotiating

with the DOJ and SEC to resolve criminal charges for improper drug marketing and kickbacks to doctors.

29. In or about December 2012, Vivian Shi, the head of government affairs for GSK in China, was fired by the company for pretextual reasons. GSK asserted that Shi was falsifying travel expenses. However the real reason for her firing was that GSK suspected that she was a whistleblower.

30. On January 16, 2013, approximately six months after GSK's settlement with the DOJ, an anonymous whistleblower sent an email entitled "Notification of Bribery by GSK in China" to GSK's Audit Committee, Board of Directors, Executive Management, including CEO Sir Andrew Witty, assorted media relations employees, and independent auditors at PwC.

31. The e-mail contained detailed corruption allegations relating to GSK's business in China. This was a particularly serious problem for GSK because the DOJ was already conducting an investigation into GSK's China business for this very type of conduct. Moreover, the conduct that was reported was strikingly similar to the conduct that the DOJ had alleged had occurred in the United States resulting in GSK's \$3 billion payment only six months earlier, and which GSK had said it had controls in place to prevent.

32. Specifically, the January 16 whistleblower communication alleged that GSK China "has engaged in illegal marketing and large-scale bribery to sell its products to Chinese hospitals and doctors."

33. The letter contained many specific allegations. First, it alleged that, as far back as 2008, "GSK deliberately falsified its books and records in order to conceal its illegal marketing practices in China, which include bribery and promoting drugs for purposes that have not been approved by the Chinese authorities."

34. The letter included a story of a patient who nearly died after receiving the drug Lamictal for an “unauthorized, off-label use” from a hospital where GSK’s salespeople prevailed on doctors to mis-prescribe the drug. It asserted that GSK quietly paid the patient RMB 50,000 through the hospital, misrepresenting the payment in its accounting “as a payment to sponsor a hospital learning seminar,” so as to avoid incurring regulatory scrutiny, bad press, and the costs of additional testing.

35. It further alleged that, despite the incident, “GSK China still required its sales employees to market and sell Lamictal to hospitals” for inappropriate off-label uses.

36. It also detailed a “pervasive cash advance bribery scheme” pursuant to which GSK sales people “identify and target doctors who can influence purchasing decisions at their hospitals,” then forge a connection “by first taking the person to expensive lunches and dinners and then giving the decision maker nice gifts,” before finally “giving the doctors cash to win business.”

37. Describing bribing doctors with cash payments as “[t]he most effective, efficient, and favored ‘marketing’ tactic used by GSK sales personnel to win business in China,” the letter explained how GSK’s “strict quotas” on sales and loose cash expense controls create “a breeding ground for corruption that pits one employee against another to see who can pay the most bribes to win the biggest deals.”

38. It further described an unaudited cash advance system whereby sales representatives are given monthly allowances of RMB 10,000-25,000 for business purposes, with the only check on spending being expense reports that employees regularly fabricate and falsify.

39. It further described a pattern in which in “higher value” cases, “the sales employee may go beyond his monthly allotment and ‘kickback’ a percentage of the tender to the

doctor(s) involved in making the decision,” often “under the guise that it is sponsoring a seminar at the doctor’s hospital.”

40. It also alleged that GSK paid for “between 500 to 1,000 doctors . . . to go on all-expense paid international vacations” each year disguised as “conference trips.”

41. Detailed in the allegations are trips of groups of 13 to 70 doctors at a time to locations such as Brazil, India, Israel, Greece, Japan, and Hungary; for which GSK would provide all tickets and expenses, in addition to “cash to cover both meals and sight-seeing excursions.”

42. The trips, meant to influence hospital decision makers and reward “large prescribers,” were facilitated by a misleading GSK communication designed to make it appear as if doctors sought sponsorship to attend conferences on their own initiative rather than their being “selected and approached by GSK’s sales and marketing team to attend . . . due to their abilities to influence sales decisions in the future.”

43. The letter concluded by listing internal GSK actions that allegedly “corroborate the pervasive corruption.” These actions include the firing of “20 Shanghai sales employees for falsifying expenses in order to bribe doctors,” instead of engaging in a broader review and audit of China sales and marketing activities; a memorandum from the head of GSK China’s internal audit “acknowledging GSK China’s policy of paying doctors’ ‘speaking fees,’” but only recommending minor changes to the practice; GSK China’s frantic efforts to “[f]abricate a [p]aper [r]ecord” to show investment in “[a]nti-[b]ribery [c]ompliance”; internal communications from the management of sales for GSK China instructing employees “to destroy all non-compliant promotional materials and gifts”; the implementation of a new email program to delete emails older than a year with the goal of “reduc[ing] unnecessary legal costs”; and the

use of intermediaries such as the “Chinese Association Against Epilepsy” to funnel money to doctors in the course of bribery schemes.

44. The whistleblower’s blunt conclusion was that “[b]ribery in some form is involved in almost every sale GSK makes in China.”

45. On March 13, 2013, another anonymous email (from a different email address) was sent to GSK officials at their headquarters in the United Kingdom claiming that Mark Reilly, the general manager of GSK China, received a bribe in the form of sexual relations in return for his maximizing business for China Comfort Travel (CCT), which provides conference services to GSK.

46. The email explains that “CCT offers invoices and fake details of conference activities to the salesmen of GSK(China), with which the salesmen of GSK get reimbursement from the company. Through this way, the salesmen pay the money to the hospitals and doctors who prescribe medicine from GSK, so as to bump the sales amount.”

47. It further stated that CCT provided an assistant, Wu Wan, to Reilly for sex in exchange for boosting GSK’s business with CCT, and concludes: “[We] hope that GSK will look through this seriously and stop making unfair and illegal deals, otherwise we would submit the above mentioned details and relevant video clip to the Chinese government, and if necessary, we would also provide these materials to the US Department of Justice and the international press.”

48. Attached to the email is a video file that shows Mark Reilly and a female companion engaged in sexual relations in his bedroom.

**GSK Approaches Peter Humphrey to Investigate Vivian Shi**

49. On April 15, 2013, a former client of ChinaWhys called Peter Humphrey and told him that he wanted to introduce him to GSK, which had an urgent matter to discuss with Humphrey.

50. At around 7:00 that evening, Peter Humphrey and Yingzeng Yu met in GSK China's Xizang Middle Road office in Shanghai with Mark Reilly, CEO of GSK (China) Investment Co., April Zhao, Legal Counsel of GSK China, and Brian Cahill, also legal counsel.

51. At the meeting, the GSK officials, led by Cahill, said they believed that Vivian Shi, a former GSKCI government affairs director who had been terminated in December 2012, had orchestrated what the GSK officials described as a "smear campaign" against GSK. They said the "smear campaign" involved 23 emails sent to Chinese governmental entities throughout China as well as a letter to top GSK management alleging widespread corruption in GSK's Chinese pharmaceutical and vaccine businesses, with direct approval of senior management.

52. The GSK officials told Humphrey and Yu that Shi had been terminated for expense fraud and had a "reputation" for being "nasty." They also said that Shi had left her previous jobs under "unhappy circumstances" and had acted "vengefully" towards her former employers. These statements were intended to and did create the impression that Shi was a disgruntled, terminated employee with a motivation to make false accusations.

53. The GSK officials knew that the allegations were *not* false. Indeed, they knew full well their truth and had been engaging in a corrupt effort to locate and bribe Chinese officials in order to prevent their illegal conduct from being exposed. It had only been a matter of months since the company paid billions of dollars in fines to the United States and it remained under the scrutiny of the DOJ and SEC. The GSK officials also knew that Shi had powerful unidentified

allies within the Communist Party elite in Shanghai and that it was therefore extremely dangerous to investigate her.

54. The GSK officials also described to Humphrey and Yu a March 16, 2013 email sent to GSK global CEO Andrew Witty and other senior officials, including the global head of compliance and general counsel, alleging that GSK used its travel agent to channel kickbacks to customers and doctors.

55. They also indicated that attached to the March 16 email was a video that showed Reilly having sex with a Chinese woman, who Reilly claimed was his “regular girlfriend.”

56. During the April 15 meeting, Peter Humphrey asked GSK officials for copies of the anonymous whistleblower allegations, but GSK refused to provide them.

57. Instead, the GSK officials stressed that GSK had improved its compliance mechanisms following earlier corruption and other illegal activities that led to the settlement with the DOJ.

58. In particular, GSK referred to the establishment of a whistleblowing system as a concrete step it had taken to show the DOJ how seriously it was taking corruption. GSK officials also stressed the development of a “compliance culture” to satisfy the DOJ and indicated that GSK had since “found more incidents of theft from the company rather than violation of compliance.” This was, of course, false. GSK knew full well that the bribery scheme had occurred, and the utter failure of its compliance efforts is evidenced by the remediation and implementation of anti-corruption measures the SEC ordered GSK to take in 2016.

59. The GSK officials told Humphrey and Yu that GSK had “launched internal investigations over the validity of [Shi’s] allegations but did not find any of the allegations to be

true.” This statement was false, because the GSK officials knew the accusations were true. Indeed, as would later be revealed, the illegal scheme was conducted at the direction of Reilly.

60. The GSK officials reiterated that, in terms of the allegations, “there is nothing there,” claiming that they had uncovered only minor irregularities, like a license issue in Beijing that resulted in a negligible fine. This statement was knowingly false.

61. Humphrey and Yu offered to investigate the whistleblower allegations, but GSK declined. GSK instead asked Humphrey and Yu to “conduct a background investigation on Shi” in addition to finding whatever they could about the sex video.

62. Plaintiffs accepted the GSK officials’ representations that they had thoroughly investigated the whistleblower allegations and that there was “nothing there.” On that basis, Humphrey agreed to conduct “a discreet information search on Shi, her activities, affiliations, track record with past employers, contacts and political influence, and an assessment of the potential risks that she could pose to GSK if she were hostile, and to gather any available information indicating that [she] . . . could have orchestrated a smear campaign against GSK and Mark Reilly.”

63. Humphrey and Yu’s mission to obtain information on the whistleblower was predicated on the false information supplied by GSK that the whistleblower allegations were unfounded and that she was attempting to extort the company. Under this set of assumptions, Humphrey and Yu understood that undermining the whistleblower’s credibility and determining the extent of her connections and influence would be essential to limiting the efficacy of her extortion.

**Humphrey and Yu Begin Their Investigation in Reliance on GSK's False Representations**

64. Following the April 15, 2013 introductory meeting, Humphrey emailed April Zhao, copying Reilly and Yu, to obtain the necessary information on Shi to draft an investigation proposal. Humphrey also followed up with a phone call and reiterated his request for the anonymous whistleblower allegations.

65. On April 19, Silvia Feng of ChinaWhys went to GSK's Shanghai office to obtain Shi's data. In addition to basic identification information, GSK provided a copy of an allegation against Shi retrieved from a social networking platform about her vengeful personality and her getting officials in Hong Kong to investigate her former boss at Johnson & Johnson. This information was intended to cause Plaintiffs to believe that Shi was making false accusations.

66. Three days later, Humphrey asked once again for copies of the whistleblower allegations against GSK, which were again withheld.

67. On May 10, 2013, GSK Audit Chair Judy Lewent and other recipients received another email from the same anonymous email address as the January 10 whistleblower email. In this email, the whistleblower alleged "that GSK China continues to engage in the systematic bribery of doctors," and focused on the sales activities for GSK China's Botox business.

68. The email discussed the "Vasily Scheme" whereby GSK pays doctors based on their prescription numbers, using sales representatives' personal accounts as intermediaries. It also detailed the use of private email addresses to circumvent investigations and claims to have emails, presentations, and spreadsheets that lay bare the scheme. It further described a pay-to-prescribe scheme that funnels money for doctors through a central source at Beijing Union Medical College and a scheme of lecture fee payments to doctors "simply to incentivize and reward doctors for prescribing Botox," regardless of whether the doctor delivers a lecture. It

“encourage[d] GSK to engage independent counsel who reports directly to the audit committee to investigate these serious issues and then to make a full accounting to the Chinese regulatory authorities, the U.K.’s Serious Fraud Office, and the SEC and DOJ.”

69. GSK did not inform Humphrey or Yu of this letter.

70. On June 6, Humphrey sent an Investigation Report for “on Shi to Zhao and Cahill, copying Yu, ChinaWhys project manager Zhao Qing, and Jennifer Huang.

#### **Media Coverage of GSK’s Alleged Bribery Begins**

71. On June 12, 2013, less than a week later, *The Wall Street Journal* published an article about the anonymous whistleblower’s allegations of bribery in China. The piece reported that GSK “is investigating allegations from an anonymous tipster that its sales staff in China was involved in widespread bribery of doctors to prescribe drugs, in some cases for unauthorized uses, between 2004 and 2010.”

72. The article summarized the whistleblower allegations as follows: “According to emails and other documents reviewed by the Wall Street Journal, the tipster has alleged that Glaxo’s China sales staff provided doctors with speaking fees, cash payments, lavish dinners and all-expense-paid trips in return for prescribing the drug firm’s products.”

73. The article further described allegations “that between 2004 and 2010, Glaxo regularly gave cash to its sales staff in China, and that some of it went directly to doctors at Chinese hospitals in return for agreeing to prescribe drugs to patients. Some sales staff then submitted fraudulent expenses to account for the funds.”

74. The article included a reference to the allegations described above about the near death of a patient due to off-label Lamictal use.

75. The article also referenced GSK's efforts "to repair its image after recent multibillion-dollar settlements with U.S. regulators tied to drug-marketing tactics," in which GSK "admitted marketing practices relating to some of its drugs were illegal."

76. The article noted that GSK "is also being investigated by U.S. authorities over whether it paid bribes to foreign government officials," noting that CEO Andrew Witty "has said making the company more transparent is a priority." Specifically with regard to the FCPA investigation, the article notes that GSK disclosed in a regulatory filing the previous year that the DOJ and SEC investigations were ongoing.

77. GSK confirmed to the *Journal* reporters the firing of 20 Shanghai sales employees alleged to be involved in bribery activities but maintained that they were fired because of "inappropriate expense claims and there was no evidence the funds were used to bribe health-care professionals."

78. The article included the following statement from a GSK spokesperson: "Over the last four months we have used significant resources to thoroughly investigate each and every claim from this single, anonymous source and have found no evidence of corruption or bribery in our China business."

**GSK Asks Humphrey and ChinaWhys Overtly To Obstruct the Chinese Government Investigation, Humphrey Refuses, and Reilly Flees China**

79. On June 17, 2013, following the *Wall Street Journal* article and follow-on media attention, and after Humphrey had provided GSK with his report on Shi, GSK senior legal counsel Jennifer Huang emailed Humphrey asking ChinaWhys to identify the "source" of the whistleblower email and the Mark Reilly sex tape email and "any background information of the

email address of the Whistle blower” as well as “back-end information” for certain “mini-blog account[s].”

80. On June 26, 2013, June Soon, Executive Secretary of Asia Pacific for GSK at GSK Pte Ltd. sent two whistleblower emails as attachments to her message to Humphrey and ChinaWhys manager Zhao Qing. Humphrey was in the United States at the time.

81. On June 27 and 28, the police raided multiple GSK China offices,

82. Following those raids, while Humphrey was still in the United States, GSK senior legal counsel Jennifer Huang asked ChinaWhys to investigate the Public Security Bureau (PSB) and to “prepare an Organic analysis ASAP on the Chinese political regime, particularly on Chinese Communist Party Regime, PSB, and state council with official’s name identified.”

83. Humphrey and Huang had a phone call that same day, while Humphrey was still in the United States. Huang said she wanted to investigate the PSB “to find out who’s who in the investigation.” Humphrey became concerned that GSK was seeking to obstruct the investigation by Chinese authorities and replied that he could not do anything that could be deemed as violating state secrets and thus could only use public information for his research.

84. On July 1, GSK China’s head of business development, Leslie Chang, asked Humphrey to investigate various government organs. Chang asked Humphrey to look into the Ministry of Public Security, the Economic Crimes Investigation Department and its relationship “to the ministry and local provincial PSB,” and the “relationship between the Ministry of PSB and the Political Bureau of the Central Committee.” Further, Chang instructed Humphrey to “provides [sic] names and titles of key officials.”

85. Humphrey refused.

86. On July 1, 2013, Mark Reilly's personal assistant Maggie Zheng contacted Humphrey, who had just arrived back in China from the United States, to arrange a meeting with Reilly the following day.

87. Humphrey and his colleague Zhao Qing met Reilly in a meeting room in the Marriott Hotel at Tomorrow Square on Nanjing Road in Shanghai that Reilly had booked because the PSB were in his office. Reilly told Humphrey that Vivian Shi had "read your report and she will be coming after you."

88. Reilly sought advice, and Humphrey stated ChinaWhys could "no longer provide service," instead telling Reilly to retain a crisis management service.

89. Reilly told Humphrey he was planning to leave China the following day for London.

90. The following day, Mark Reilly fled China.

#### **Humphrey and Yu Are Arrested**

91. As Reilly predicted, the retaliation for the attack he had orchestrated on Vivian Shi in an attempt to cover up his and GSK's own crimes came swiftly, but it fell, predictably, on Humphrey and Yu, since Reilly was by then safely back in Britain. On July 10, 2013, Shanghai police raided ChinaWhys' office in that city as well as the Humphrey's Beijing home. These raids provided a chilling indication of what Yu and Humphrey were about to endure at the hands of the Chinese authorities. The police placed Humphrey (age 57) and Yu (age 60) in handcuffs and took them to the police headquarters to be interrogated until past midnight. A police officer told Humphrey: "This was ordered from above. This is related to GSK."

92. Humphrey and Yu were separately transported to Shanghai Detention House and placed in crowded cells. Humphrey's cell contained 12 inmates in a space of roughly 15 square

meters; Yu's cell contained 10 inmates. There was no furniture in the cells, no hot water for washing, no clean bedding, and no private toilet. Humphrey and Yu were not allowed to write letters or make phone calls; even to their families and lawyers. Both were forced to sit on the floor for hours continuously, causing extreme pain, and they were deprived of fresh air and sunlight for months at a time.

93. On August 16, 2013, Humphrey and Yu were formally arrested.

**Humphrey and Yu Are Tried and Convicted in a "Show Trial" and Sent to Prison**

94. The prosecution that followed was abusive and lacking in any due process. Humphrey and Yu's attorneys requested bail twice for health and family reasons, but Shanghai police denied the requests, claiming "this was the first time Shanghai had arrested foreign investigators, and therefore the case would be used to make an example of the kind, regardless whether guilty or innocent."

95. Prior to their trial, Humphrey and Yu were repeatedly deceived by police and prosecutors who found excuses to delay any judicial process as a means to keep them detained. They misled Humphrey and Yu into appearing in a fake "media interview," and paraded them on television dressed in orange vests, handcuffed, and locked in a metal cage. They told them to make an apology in exchange for leniency, and then broadcast nationwide what they called a "confession of crime." The prosecutors systematically blocked the rights of the defense attorneys to view the case files.

96. The show "trial" took place on August 18, 2014. The trial generally proceeded without anything resembling due process. For example, the prosecutors fabricated witness statements for "witnesses" who never testified in court. But none of that was necessary, since the judge had long before made up his mind about the outcome of the case.

97. Humphrey and Yu were led to understand that their prosecution was procured at the behest of Shi, seeking revenge against them for the investigation that they conducted based upon the false statements of GSK. On August 8, 2014, after already having been detained for 13 months without a trial, Humphrey was sentenced to 2.5 years in prison; Yu was sentenced to 2 years.

98. Humphrey was transferred to Qingpu Prison and Yu to Shanghai Women's Prison to serve out their terms. While in prison, Humphrey and Yu suffered from a wide range of maltreatment ranging from passive denial and ignorance of requests for basic needs, to active and aggressive cruelty at the hands of prison guards.

99. In September 2013, while still at the detention center awaiting trial, Humphrey had noticed his prostate was swollen and urination was irregular, and thus requested medical treatment from resident doctors at the Detention House. Humphrey underwent an ultrasound that showed his prostate had enlarged and calcified. Despite the guidance of civilian doctors that extensive additional tests were necessary, officers prevented Humphrey from undergoing any further tests. Humphrey only underwent some of the necessary tests some 21 months after his detention following the intensified entreaties of the British consulate; a delay that allowed his cancer to develop untreated. Following two years in prison without adequate access to care, Humphrey was diagnosed with life-threatening prostate cancer that a specialist physician indicated could have been prevented had Humphrey received appropriate medical attention at the beginning of his time in prison.

100. Humphrey also experienced growing neck pain that had begun when officers kicked a door into his face during their raid of China Whys' office. Prison officials denied Humphrey's family's request to give him a neck brace to alleviate his suffering.

101. Prison officers told inmates that Humphrey was a British spy and ordered them not to associate with or talk to him, effectively isolating Humphrey from the moment of his arrival.

102. While in Qingpu Prison, Humphrey suffered various other cruel and embarrassing treatment, including: officers scattering his belongings during cell searches; pressuring him to sign a confession to gain privileges or avoid solitary confinement or an extended sentence; parading him around in his prison uniform, handcuffed and leg-manacled in front of the general public on the rare occasion towards the end of his captivity when he was taken to visit a hospital for medical treatment; and preventing him from telephoning family members and his consuls after he learned that he a prostate tumor. He also was given a diet lacking basic nutrients such as proteins, vitamins and minerals, and after his release found his calcium and vitamin D levels dangerously low.

103. Yu's treatment, though not as vindictive and capricious as Humphrey's, was similarly harsh, causing her severe distress. During her 23 month incarceration, including at Shanghai Women's Prison, Yu was deprived of fresh air and sunlight and not allowed to spend any time outside or exercising. She was not permitted to telephone her family at all, unlike other prisoners, and her correspondence was severely curtailed and censored. She also was given a diet lacking basic nutrients such as proteins, vitamins and minerals, and after her release found her calcium and vitamin D levels dangerously low. A London doctor found these levels to be at only a quarter of the required level. She was also suffering from blood in her urine and a damaged kidney.

104. Word of Humphrey and Yu's ill treatment eventually reached Western media, including *The Telegraph*, which noted that while in the pre-trial detention center for 14 months

the couple could not see each other save for “occasionally snatch[ing] glimpses of each other through windows or doors” on their way to interrogations. The same article noted that Humphrey and Yu’s son was not permitted to visit his parents in jail.

105. On June 9, 2015, Humphrey and Yu were released from prison.

106. After a brief period of house arrest, and a battery of threats, Humphrey and Yu were finally permitted to leave and were deported from China on June 17, 2015.

107. Throughout their incarceration, Humphrey’s teenage son was denied access to the family’s assets and had to live on the charity of friends.

**GSK Lies About its Knowledge of Corruption and Refuses to Admit Why it Hired Plaintiffs.**

108. Following the arrest of four senior GSK China executives in July of 2013, GSK’s global CEO, Sir Andrew Witty, stated “[i]t appears that certain senior executives in the Chinese business have acted outside of our processes and our controls to both defraud the company and the Chinese healthcare system.” Witty claimed, however, that GSK’s head office in London lacked knowledge of the whistleblower’s allegations and “had no sense of this issue.”

109. This made no sense, since the previous month, GSK effectively admitted that it did “have a sense” of the issue, since it announced that its “four-month internal investigation into allegations of bribery and corruption in China found ‘no evidence of corruption or bribery in our Chinese business.’”

110. Witty argued, nonsensically, that the previous whistleblower allegations were “quite different” from the more recent charges, saying “[t]hey are two completely different sets of issues: we fully investigated the first and of course this has now surfaced in the last couple of weeks.”

111. This was a lie, since what “surfaced” in the PSB investigation and raids of GSK offices in July was precisely the illegal activity that the whistleblower had documented and threatened to reveal in January.

112. Approximately a year later, while Humphrey and Yu were detained and still awaiting trial, GSK issued a “Statement in Response to Recent Media Coverage Related to Our China Business”. The statement claimed that GSK had investigated “allegations made in early 2013 about GSK’s business in China . . . over several months with the support of external legal and audit advice” and that, with the exception to minor expense claims fraud, “this investigation did not find evidence to substantiate the specific allegations made in the whistleblower emails.”

113. GSK further stated that its China business “hired ChinaWhys in April 2013 to conduct an investigation following a serious breach of privacy and security,” the Reilly sex tape, but that ChinaWhys was “not hired to investigate the substance of the allegations of misconduct made by the whistleblower.” This statement was misleading at best since the “breach of privacy and security” was actually a whistleblower reporting directly on the corruption allegations.

114. This misleading statement by GSK prolonged Humphrey and Yu’s incarceration, because British diplomats attempting to intervene on behalf of Humphrey and Yu did not have accurate information about what had led to their arrest.

115. For example, an article published in *The Telegraph* on July 6, 2014 quotes a British official involved in efforts to intervene on behalf of Yu and Humphrey: “GSK refused to reveal the reasons why they had originally employed [Humphrey’s] services and that this impeded British attempts to intervene on his behalf.” “GSK were really cagey. They just kept saying it was routine work and kept the information deliberately vague. When we went to the Chinese we were arguing with one hand tied behind our backs.”

**GSK Admits Corruption in China**

116. On September 19, 2014, GSK issued a Statement of Apology to the People of China in which it announced that “GSK China Investment Co. Ltd (GSKCI) has been identified according to Chinese law to have offered money or property to non-government personnel in order to obtain improper commercial gains, and has been found guilty of bribing non-government personnel.” On September 19, 2014, GSK was fined \$492 million for its bribery activities in China “in the biggest such penalty ever imposed by a Chinese court.”

117. Mark Reilly, the CEO of GSK China, was convicted for his part in the bribery scheme and sentenced to three years prison with a four-year reprieve and ordered deported, meaning he will never serve his sentence.

118. Four Chinese nationals were also given prison sentences along with reprieves.

119. GSK’s statement includes an apology “for the harm caused to individuals who were illegally investigated by GSKCI.” This apology appears to be directed at Vivian Shi, the former employee GSK had directed ChinaWhys to investigate, and contradicts GSK’s other statements about ChinaWhys.

120. On September 30, 2016, GSK plc entered into a settlement agreement with the SEC relating to its bribery scheme in China. The company agreed to pay \$20 million—this in addition to what it paid to the Chinese authorities. In connection with that settlement, the company must also make regular reports to show that it is overhauling its lax internal controls and is instituting basic safeguards to prevent corruption going forward. The SEC Order and associated documents and findings of fact are incorporated herein by reference.

**CAUSES OF ACTION**

**First Cause of Action**

**Violations of 18 U.S.C. § 1962(c) (Racketeering)**

121. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

122. Each of the individuals and corporate entities is a “person” within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise, the GSK Drug Bribery and Promotion Enterprise, through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

123. The GSK Drug Bribery and Promotion Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendant corporations, including their employees, agents and external consultants, specifically former employees Mark Reilly, Gary Zhang, Liang Hong, April Zhao Hongyan, and others convicted of crimes related to GSK activities; unnamed doctors in the United States, China, and other countries who accepted bribes and kickbacks from GSK; Sino-American Tianjin Smith Kline & French Laboratories Ltd; various unnamed travel agents, conference organizers, and other third-party service providers; various Chinese health care providers; the Chinese Association Against Epilepsy; and other as yet unknown individuals and entities. All entities are persons within the meaning of 18 U.S.C. § 1961(3) and acted to enable Defendants to bribe medical doctors and other health care providers to prescribe GSK products to patients, even in cases when such prescription was medically inappropriate or dangerous; to deceive the DOJ and other regulators regarding corporate practices, compliance protocols and the integrity of their internal controls; and to mislead Humphrey, Yu, and ChinaWhys into performing a fraudulent investigation designed to cover up illegal and pernicious activities in China and thwart investigations into those activities. The GSK Drug Bribery and Promotion Enterprise functioned as an ongoing organization and continuing

unit. The GSK Drug Bribery and Promotion Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. Defendants, in concert with other participants in the GSK Drug Bribery and Promotion Enterprise, created and maintained systematic links for a common purpose—to maximize and protect GSK profits through the creation and management of a massive scheme of bribery and fraud, whereby GSK sales representatives gave goods, services, and cash to doctors in exchange for aggressively prescribing drugs and vaccines, often for unapproved and inappropriate uses, and thus boosting corporate revenue. Each of the participants in the GSK Drug Bribery and Promotion Enterprise received substantial revenue from the scheme to bribe doctors. Such revenue was significantly greater than it would have been if GSK had abided by the laws of China, the United States, and other jurisdictions and refrained from illegally providing doctors with payments for their prescribing GSK products, or if GSK had legitimately investigated and lawfully addressed the whistleblower claims in China; including reporting to and cooperating with Chinese and American regulators and law enforcement agencies. All participants in the GSK Drug Bribery and Promotion Enterprise were aware of Defendants' control over the activities of the GSK Drug Bribery and Promotion Enterprise in bribing doctors and misrepresenting, including by omission, GSK's activities to government bodies including the DOJ, with whom GSK had previously signed a Settlement Agreement. Furthermore, each portion of the enterprise benefited from the existence of the other parts.

124. The GSK Drug Bribery and Promotion Enterprise engaged in and affected interstate commerce because, *inter alia*, it sold drugs and vaccines throughout the United States and maintains relationships with various doctors and medical entities throughout the United States, and foreign commerce because it sold vaccines, drugs, and other goods and services on a

global scale, including those sales made by virtue of fraud and bribery schemes, including in the United States, China, and numerous other countries.

125. Defendants exerted control over the GSK Drug Bribery and Promotion Enterprise and management of the affairs of the GSK Drug Bribery and Promotion Enterprise.

126. Pursuant to and in furtherance of their fraudulent scheme, Defendants conducted and participated in the affairs of the GSK Drug Bribery and Promotion Enterprise through patterns of racketeering activity, including multiple acts indictable under 18 U.S.C. §§ 1341 (mail fraud); 1343 (wire fraud); 1510 (Obstruction of a criminal investigation); 1512 (tampering with witnesses); 1513 (Retaliating against a witness, victim, or an informant); 1952 (use of interstate facilities to conduct unlawful activity), and 1956 (money laundering).

127. Defendants' fraudulent scheme consisted of, *inter alia*: deliberately misrepresenting facts to Humphrey, Yu, and ChinaWhys to induce them to carry out an investigation that served GSK's political goals and provided cover for GSK's illegal activities; engaging in massive fraud and bribery schemes as detailed through the successful prosecution and conviction of GSK's China CEO and four other senior officials and the findings made by the SEC; the firing of and retaliation against whistleblowers; the bribing of various Chinese officials who would share information relating to the bribery scheme with U.S. criminal and regulatory authorities; the laundering of money through various schemes, including through false travel expenses; an array of other activities, including some which rise to the level of felonious wire fraud, including but not limited to failure to report data to the FDA, distribution of a misbranded drugs due to inadequate directions for use, distribution of a misbranded drug due to false and misleading labeling, providing doctors with kickbacks, fraudulently misleading sales staff and medical professionals through the promotion of false information and suppression of unfavorable

information, and other illicit activities as detailed in GSK's 2012 DOJ Settlement Agreement; improperly and illegally withholding or distorting knowledge of such schemes from the DOJ and other law enforcement and regulatory bodies; and violating compliance measures agreed upon with the DOJ by ignoring reporting requirements as pertaining to corporate integrity.

128. Defendants' use of the mail and wires to perpetuate its fraud involved thousands of communications, including, but not limited to:

- a. Communications with and among the enterprise participants instructing, permitting, encouraging, and carrying out fraud and bribery through cash payments and kickbacks to medical doctors in China, the United States, and other countries, as admitted by Mark Reilly and four Chinese officials in guilty pleas in Chinese court, including Gary Zhang and Liang Hong;
- b. Communications with travel agents and other third-party service providers to facilitate sham seminars, conferences, and other events with the purpose of providing travel and other gifts as inducements to and compensation for doctors prescribing GSK products;
- c. Communications with Humphrey, Yu, and other ChinaWhys employees, including those undertaken with Humphrey while he was in the United States (19-29 June 2013), fraudulently inducing them to carry out a contrived investigation to serve GSK's political goals and as a means of setting up Humphrey, Yu, and ChinaWhys to shield GSK from consequences of its illegal actions in China, substituting Humphrey, Yu, and ChinaWhys as a target and scapegoat;
- d. Receiving the proceeds in the course of and resulting from Defendants' improper scheme in the form of profits from GSK product sales;

- e. Failure, in communication with the DOJ and other regulators and law enforcement agencies, to abide by the terms of GSK's 2012 Settlement Agreement and attendant Administrative Resolution, including a five-year Corporate Integrity Agreement with the Office of the Inspector General of the Department of Health and Human Services;
- f. Transmittal and receipt of monies from insurance companies, medical organizations, patients, and health care providers;
- g. Transmittal and receipt of payments in exchange for, directly or indirectly, activities in furtherance of the GSK Drug Bribery and Promotion Enterprise.

129. At all times during the fraudulent scheme, Defendants' and the Fraud Participants had a legal and ethical obligation of candor to and honest dealing with public and private payors, physicians and the medical community, Humphrey, Yu, China Whys, Chinese regulators and law enforcement bodies, and United States government bodies such as the DOJ and the SEC.

130. The conduct of the GSK enterprise described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendants' decisions and activity in connection with the GSK enterprise to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

131. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiffs. Each such racketeering activity was related, had similar purposes, involved similar or the same participants, and methods of commission, and had similar results affecting the same or similar victims, including Plaintiffs. Defendants' racketeering activities were part of their ongoing business and constitute a continuing threat to the property of Plaintiffs.

132. Plaintiffs have been injured in their property by reason of these violations in that, among other things, Plaintiffs' business was destroyed and their prospective business ventures eviscerated by Defendants' pattern of racketeering activity.

133. The injuries to Plaintiffs were directly and proximately caused by Defendants' racketeering activity.

134. Plaintiffs, both directly and indirectly, relied on the representations as to the falseness of the whistleblower's claims as made by the Defendants. Because Defendants controlled all knowledge regarding the whistleblower allegations, including the anonymous charges themselves, which Plaintiffs were not permitted to read for weeks despite repeated requests, Plaintiffs were obligated to rely on Defendants' representations about the whistleblower's identity and the veracity of her claims. Further, Defendants perpetuated this reliance by taking the steps itemized above to target Plaintiffs' investigation at Vivian Shi and suppress the dissemination of information that would have allowed them to better understand the validity of the whistleblower allegations and from whom they may have originated.

135. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are liable to Plaintiffs for three times the damages sustained, plus the costs of this suit, including reasonable attorneys' fees.

136. By reason of the foregoing, and as a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiffs have suffered damages. Plaintiffs are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

137. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in a sum that exceeds the jurisdiction of all lower courts.

**Second Cause of Action**

**Violation of 18 U.S.C. § 1962(d) (Conspiracy)**

138. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

139. Section 1962(d) of RICO provides that “shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section.”

140. Defendants have violated 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962 (c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the GSK enterprise described previously through a pattern of racketeering activity. The corporate defendants conspired with, inter alia, Mark Reilly and others to promote the red herring investigation of Vivian Shi as a whistleblower making false claims and suppress evidence of GSK’s fraud and bribery in China.

141. Defendants’ co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiffs of money.

142. The nature of the above-described acts of Defendants’ co-conspirator’s acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity demonstrated through related and continuous acts.

143. As a direct and proximate result of Defendants’ overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c),

Plaintiffs have been and are continuing to be injured in their business or property as set forth more fully above.

144. Defendants sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

- a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;
- b. Multiple instances of mail fraud violations of 18 U.S.C. §§ 1341 and 1346;
- c. Multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346;
- d. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952;
- e. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1510 (Obstruction of a criminal investigation);
- f. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1512 (tampering with witnesses);
- g. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1513 (Retaliating against a witness, victim, or an informant); and
- h. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1956 (money laundering).

145. Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiffs have been injured in their property by reason of these violations in that Plaintiffs Humphrey and Yu have been jailed and put out of business, which they would not have suffered had Defendants not conspired to violate 18 U.S.C. § 1962(c).

146. Injuries suffered by Plaintiffs were directly and proximately caused by Defendants' racketeering activity as described above.

147. Plaintiffs directly relied on the racketeering activities of the Defendants and the GSK enterprise. Plaintiffs, both directly and indirectly, relied on the representations as to the identity of the whistleblower and the falsity of her claims. Because Defendants controlled all knowledge of such allegations and their veracity, Plaintiffs were obligated to rely on Defendants' misrepresentations regarding the whistleblower and predicate schemes of fraud and bribery. Defendants perpetuated this reliance by taking the steps itemized above to target Plaintiffs' investigation at Vivian Shi and suppress the dissemination of information that would have allowed them to better understand the validity of whistleblower allegations and from whom they may have originated.

148. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are liable to Plaintiffs for three times the damages Plaintiffs have sustained, plus the cost of this suit, including reasonable attorney's fees.

149. By reason of the foregoing, and as a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiffs have suffered damages. Plaintiffs are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

### **Third Cause of Action**

#### **State Claim: Fraud**

150. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

151. Defendants asked Plaintiffs to investigate Vivian Shi, a highly connected Chinese national who had been head of Government Affairs for Defendants in China. Defendants represented to Plaintiffs that they believed that Shi had sent anonymous letters making false accusations, and that they wanted to assess the potential damage that Shi could inflict on the company by spreading untrue rumors. Defendants also represented to Plaintiffs that they had investigated the allegations contained in the anonymous letters and determined that they were untrue.

152. These statements were knowingly false when made, as Defendants knew that the accusations in the anonymous letters were not false. In fact, the individual Defendant officers who made the statements had orchestrated the illegal conduct that was the subject of the allegations. However, Defendants wanted to frame Shi as an extortionist in order to prevent the truth of the allegations from coming to light.

153. Defendants made these false statements with the intent to induce Plaintiffs to rely on them and to create a dossier on Shi to bolster the false assertion that she was an extortionist making false claims and hide the truth about the allegations. They knew that Plaintiffs would not agree to conduct an investigation for illegal purposes, so Defendants hid their true motives and actively concealed facts known to them.

154. Defendants' misrepresentations were material, and caused Plaintiffs to agree to conduct the initial investigation.

155. Plaintiffs justifiably and directly relied on Defendants' affirmations, including because Defendants continually denied Plaintiffs permission to read the original emails until after they had investigated and prepared a report on Shi.

156. Defendants' misrepresentations were the proximate cause of Plaintiffs' arrest. Plaintiffs were arrested and imprisoned for investigating Vivian Shi, which they would not have done had Defendants not hired them and misrepresented the purpose and nature of the investigation.

**Fourth Cause of Action**

**State Claim: Intentional Infliction of Emotional Distress**

157. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

158. Defendants intentionally misled Plaintiffs and induced them into investigating an innocent person under the guise that she was making false allegations in an attempt at extortion.

159. Defendants intentionally placed Plaintiffs at risk by causing them to investigate someone connected to the Chinese government in order to aid Defendants' attempt to suppress investigations of their wrongdoing.

160. Defendants intentionally continued to lie about Plaintiffs' involvement in the case, including after they were arrested, making it appear as if they had been conducting a rogue investigation.

161. Defendants' conduct was extreme and outrageous, and went beyond all bounds of decency, because it put Plaintiffs in danger and caused them to be arrested and imprisoned by Chinese authorities. Defendants' continued false public statements about Plaintiffs were extreme and outrageous because they obstructed the British and American authorities from being able to fully assist Plaintiffs.

162. Defendants' conduct was a direct cause of Plaintiffs' severe emotional distress.

163. Defendants' conduct was a proximate cause of Plaintiffs' severe emotional distress, as Defendants' misrepresentations to Plaintiffs caused them to investigate an innocent person with powerful allies in the Chinese government. Defendants' misrepresentations caused Plaintiffs to be arrested and imprisoned by Chinese authorities for twenty three months under conditions of neglect and abuse that caused them severe emotional distress.

**Fifth Cause of Action**

**State Claim: Negligent Infliction of Emotional Distress**

164. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

165. Defendants intentionally or negligently misled Plaintiffs and induced them into investigating an innocent person under the guise that she was making false allegations in an attempt at extortion.

166. Defendants intentionally or negligently placed Plaintiffs at risk by causing them to investigate someone connected to the Chinese government in order to aid Defendants' attempt to suppress investigations of their wrongdoing.

167. Defendants intentionally or negligently continued to lie about Plaintiffs' involvement in the case, including after they were arrested, making it appear as if they had been conducting a rogue investigation.

168. Defendants' conduct was at a minimum negligent.

169. Defendants' conduct was a direct cause of Plaintiffs' severe emotional distress.

170. Defendants' conduct was a proximate cause of Plaintiffs' severe emotional distress, as Defendants' misrepresentations to Plaintiffs caused them to investigate an innocent person with powerful allies in the Chinese government. Defendants' misrepresentations caused

Plaintiffs to be arrested and imprisoned by Chinese authorities for twenty three months under conditions of neglect and abuse that caused them severe emotional distress.

**Fifth Cause of Action**

**State Claim: Civil Conspiracy**

171. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

172. Defendants have conspired to deliberately misrepresent facts to Plaintiffs to induce them to carry out a misguided investigation that served Defendants' political goals, and provided cover for their illegal activities.

173. Defendants have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of their conspiracy, including:

- a. Engaging in massive fraud and bribery schemes as detailed through the successful prosecution and conviction of GSK's China CEO and four other senior officials;
- b. Failure to report data to the FDA;
- c. Distribution of misbranded drugs due to inadequate directions for use;
- d. Distribution of a misbranded drug due to false and misleading labeling;
- e. Providing Doctors with kickbacks;
- f. Fraudulently misleading sales staff and medical professionals through the promotion of false information and suppression of unfavorable information;
- g. Other illicit activities as detailed in GSK's 2012 DOJ Settlement Agreement;
- h. Improperly and illegally withholding or distorting knowledge of such schemes from the DOJ and other law enforcement and regulatory bodies;

- i. Intimidating witnesses through an overreaching internal investigation in China facilitated by an outside law firm; and,
- j. Violating compliance measures agreed upon with the DOJ by ignoring reporting requirements as pertaining to corporate integrity.

174. Plaintiffs have been injured in their property by reason of these violations in that Plaintiffs Humphrey and Yu would not have been indicted, convicted, and jailed in China, nor would they have had their business shuttered, their health deteriorate without treatment, or their prospective business ventures eviscerated had Defendants not engaged in this civil conspiracy.

175. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in a sum that exceeds the jurisdiction of all lower courts.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for relief as follows:

1. On Plaintiffs' RICO claims: compensatory damages, and enhancement of damages Plaintiffs have sustained as a result of Defendants' conduct as may be permitted under the relevant statutes, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorneys' fees;
2. On Plaintiffs' fraud, intentional infliction of emotional distress, negligent infliction of emotional distress and civil conspiracy claims: compensatory and punitive damages in an amount to be determined at trial.

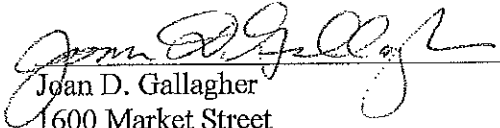
#### **JURY DEMAND**

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs demand trial by jury on all issues so triable.

Dated: Philadelphia, Pennsylvania  
November 15, 2016

Respectfully Submitted,

GALLAGHER & TURCHI

  
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*To be admitted Pro Hac Vice (Applications Pending)*

Filed and Attested by the  
Office of Judicial Records  
24 OCT 2018 12:05 pm  
A. SILIGRINI



# EXHIBIT - B

Filed and Attested by the  
Office of Judicial Records  
24 OCT 2018 12:05 pm  
A. SILIGRINI



# EXHIBIT - C

UNITED STATES COURT OF APPEALS  
FOR THE THIRD CIRCUIT

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No. 17-3285

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PETER HUMPHREY; YU YINGZENG; CHINAWHYS COMPANY LTD,  
Appellants

v.

GLAXOSMITHKLINE PLC; GLAXOSMITHKLINE LLC

---

On Appeal from the United States District Court  
for the Eastern District of Pennsylvania  
(D. C. Civil No. 2-16-cv-05924)  
District Judge: Honorable Nitza I. Quinones Alejandro

---

Argued on May 24, 2018

Before: McKEE, SHWARTZ and NYGAARD, Circuit Judges

**JUDGMENT**

This case came on to be heard on the record from the United States District Court for the Eastern District of Pennsylvania and was argued on May 24, 2018.

Upon consideration whereof,

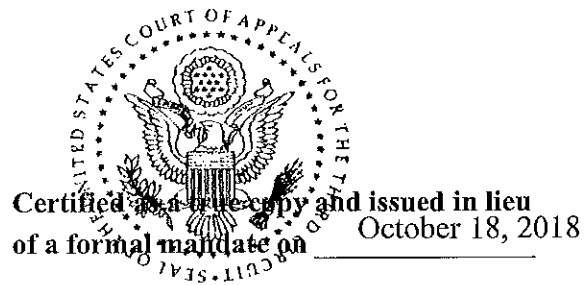
**IT IS ORDERED AND ADJUDGED** by this Court that the judgment of the District Court entered September 29, 2017 be and the same is hereby **AFFIRMED**. All of the above in accordance with the Opinion of this Court. Costs are taxed against Appellants.

**ATTEST:**

s/ Patricia S. Dodszuweit

Clerk

Dated: September 26, 2018



Teste: *Patricia A. Dodszuweit*  
Clerk, U.S. Court of Appeals for the Third Circuit

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PETER HUMPHREY, *et al.*  
*Plaintiffs*

v.

GLAXOSMITHKLINE, PLC., *et al.*  
*Defendants*

CIVIL ACTION

NO. 16-5924

ORDER

AND NOW, this 29<sup>th</sup> day of September 2017, upon consideration of the *motion to dismiss* filed by Defendants GlaxoSmithKline plc and GlaxoSmithKline LLC ("Defendants"), [ECF 19], the response in opposition filed by Plaintiffs Peter Humphrey, Yu Yingzeng, and ChinaWhys Company Ltd. ("Plaintiffs"), [ECF23], Plaintiffs' declaration in support of their response, [ECF 24], Defendants' reply, [ECF 25], and Defendants' notice of supplemental authority, [ECF 26], it is hereby **ORDERED**, for the reasons set forth in the accompanying Memorandum Opinion filed on this day, that Defendants' motion to dismiss is **GRANTED**, and Plaintiffs' complaint, [ECF 1], is **DISMISSED**.

BY THE COURT:

/s/ Nitza I. Quiñones Alejandro  
NITZA I. QUIÑONES ALEJANDRO  
Judge, United States District Court

A TRUE COPY CERTIFIED TO FROM THE RECORD  
DATED: OCT 19 2018  
ATTEST: Steve Thomas  
DEPUTY CLERK, UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA

Case ID: 181003237

Filed and Attested by the  
Office of Judicial Records  
24 OCT 2018 12:05 pm  
A. SILIGRINI



# EXHIBIT - D

CLOSED, APPEAL, SPECIAL

**United States District Court  
Eastern District of Pennsylvania (Philadelphia)  
CIVIL DOCKET FOR CASE #: 2:16-cv-05924-NIQA  
Internal Use Only**

HUMPHREY et al v. GLAXOSMITHKLINE PLC et al  
Assigned to: HONORABLE NITZA I QUINONES  
ALEJANDRO  
Case in other court: USCA, 17-03285  
Cause: 18:1964 Racketeering (RICO) Act

Date Filed: 11/15/2016  
Date Terminated: 09/29/2017  
Jury Demand: Plaintiff  
Nature of Suit: 470 Other Statutes:  
Racketeer/Corrupt Organization  
Jurisdiction: Federal Question

**Plaintiff****PETER HUMPHREY**

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**A TRUE COPY CERTIFIED TO FROM THE RECORD****DATED:** OCT 19 2018**ATTEST:** Steve Tomas

DEPUTY CLERK, UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA

**Plaintiff****YU YINGZENG**

represented by **JOAN D. GALLAGHER**

(See above for address)  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**JOHN T ZACH**  
(See above for address)  
*LEAD ATTORNEY*  
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**PHILIP M. BOWMAN**  
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*LEAD ATTORNEY*  
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**Plaintiff**

**CHINAWHYS COMPANY LTD**

represented by **JOAN D. GALLAGHER**  
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Date Filed	#	Docket Text
11/15/2016	<u>1</u>	COMPLAINT against GLAXOSMITHKLINE LLC, GLAXOSMITHKLINE PLC ( Filing fee \$ 400 receipt number 150189.), filed by PETER HUMPHREY, YU YINGZENG, CHINAWHYS COMPANY LTD. (Attachments: # <u>1</u> Civil Cover Sheets)(tj, ) (Entered:

		11/16/2016)
11/15/2016		Summons 2 Issued as to GLAXOSMITHKLINE LLC, GLAXOSMITHKLINE PLC. Forwarded To: Counsel on 11/16/16 (tj, ) Modified on 11/18/2016 (tj, ). (Entered: 11/16/2016)
11/15/2016		DEMAND for Trial by Jury by CHINAWHYS COMPANY LTD, PETER HUMPHREY, YU YINGZENG. (tj, ) (Entered: 11/16/2016)
12/02/2016	<u>2</u>	AFFIDAVIT of Service by Philip M. Bowman re: served Complaint and Summons upon Morgan J. Miller by email on 11/23/2016 (GALLAGHER, JOAN) (Entered: 12/02/2016)
12/12/2016	<u>3</u>	NOTICE of Appearance by NATHAN P. HELLER on behalf of GLAXOSMITHKLINE LLC, GLAXOSMITHKLINE PLC with Certificate of Service (Attachments: # <u>1</u> Certificate of Service)(HELLER, NATHAN) (Entered: 12/12/2016)
12/12/2016	<u>4</u>	NOTICE of Appearance by JAYNE RISK on behalf of GLAXOSMITHKLINE LLC, GLAXOSMITHKLINE PLC with Certificate of Service (Attachments: # <u>1</u> Certificate of Service)(RISK, JAYNE) (Entered: 12/12/2016)
12/13/2016	<u>5</u>	STIPULATION AND ORDER THAT DEFENDANTS' DEADLINE TO RESPOND OR OTHERWISE PLEAD TO PLAINTIFFS' COMPLAINT IS 1/16/2017, ETC. SIGNED BY HONORABLE NITZA I QUINONES ALEJANDRO ON 12/13/16. 12/13/16 ENTERED AND COPIES MAILED, E-MAILED.(ti, ) Modified on 12/13/2016 (ti, ). (Entered: 12/13/2016)
12/20/2016	<u>6</u>	Letter to Attorney KURT W. HANSSON re: L.R. 83.5 and 83.5.2. (eibo, ) (Entered: 12/20/2016)
12/22/2016	<u>7</u>	Disclosure Statement Form pursuant to FRCP 7.1 including GlaxoSmithKline LLC is owned through several levels of wholly owned subsidiaries by GlaxoSmithKline plc, a publicly held English limited liability company with Certificate of Service by GLAXOSMITHKLINE LLC. (Attachments: # <u>1</u> Certificate of Service)(HELLER, NATHAN) (Entered: 12/22/2016)
12/22/2016	<u>8</u>	Disclosure Statement Form pursuant to FRCP 7.1 with Certificate of Service by GLAXOSMITHKLINE PLC. (Attachments: # <u>1</u> Certificate of Service) (HELLER, NATHAN) (Entered: 12/22/2016)
12/22/2016	<u>9</u>	Disclosure Statement Form pursuant to FRCP 7.1 by CHINAWHYS COMPANY LTD.(GALLAGHER, JOAN) (Entered: 12/22/2016)
01/03/2017	<u>10</u>	MOTION for Pro Hac Vice of <i>Kurt W. Hansson</i> filed by GLAXOSMITHKLINE LLC, GLAXOSMITHKLINE PLC.Certificate of Service. (Attachments: # <u>1</u> Proposed Order)(HELLER, NATHAN) Modified on 1/4/2017 (ti, ). (FEE PAID 01/04/2017) (Entered: 01/03/2017)
01/03/2017	<u>11</u>	MOTION for Pro Hac Vice of <i>James B. Worthington</i> filed by GLAXOSMITHKLINE LLC, GLAXOSMITHKLINE PLC.Certificate of Service. (Attachments: # <u>1</u> Proposed Order)(HELLER, NATHAN) Modified

		on 1/4/2017 (ti, ). (FEE PAID 01/04/2017) (Entered: 01/03/2017)
01/04/2017	<u>12</u>	ORDER THAT THE APPLICATION OF KURT W. HANSSON, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE NITZA I QUINONES ALEJANDRO ON 1/4/17. 1/5/17 ENTERED AND COPIES & ECF APPLICATION MAILED, E-MAILED. (ti, ) (Entered: 01/05/2017)
01/04/2017	<u>13</u>	ORDER THAT THE APPLICATION OF JAMES B. WORTHINGTON, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE NITZA I QUINONES ALEJANDRO ON 1/4/17. 1/5/17 ENTERED AND COPIES & ECF APPLICATION MAILED, E-MAILED. (ti, ) (Entered: 01/05/2017)
01/05/2017	<u>14</u>	APPLICATION OF PHILIP BOWMAN, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b), <i>Statement and Certificate of Service</i> (FILING FEE PAID 1/6/17) by CHINAWHYS COMPANY LTD, PETER HUMPHREY, YU YINGZENG. (ti, ) (Entered: 01/06/2017)
01/05/2017	<u>15</u>	APPLICATION OF JOHN T. ZACH, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2 (b), <i>Statement and Certificate of Service</i> (FILING FEE PAID 1/6/17) by CHINAWHYS COMPANY LTD, PETER HUMPHREY, YU YINGZENG. (ti, ) (Entered: 01/06/2017)
01/06/2017	<u>16</u>	ORDER THAT THE APPLICATION OF PHILIP BOWMAN, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE NITZA I QUINONES ALEJANDRO ON 1/6/17. 1/9/17 ENTERED AND COPIES & ECF APPLICATION MAILED & E-MAILED.(ti, ) (Entered: 01/09/2017)
01/06/2017	<u>17</u>	ORDER THAT THE APPLICATION OF JOHN T. ZACH, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE NITZA I QUINONES ALEJANDRO ON 1/6/17. 1/9/17 ENTERED AND COPIES & ECF APPLICATION MAILED & E-MAILED.(ti, ) (Entered: 01/09/2017)
01/16/2017	<u>18</u>	MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM <i>MOTION TO COMPEL ARBITRATION OR, IN THE ALTERNATIVE, TO DISMISS COMPLAINT</i> filed by GLAXOSMITHKLINE LLC, GLAXOSMITHKLINE PLC.Memorandum of Law, Declarations, Exhibits, Certificate of Service.** (FILED IN ERROR, INCOMPLETE PDF, ATTY RE-FILED AT DOCUMENT <u>19</u> )** (Attachments: # <u>1</u> Memorandum Memorandum of Law, # <u>2</u> Text of Proposed Order Proposed Order, # <u>3</u> Certificate of Service Certificate of Service, # <u>4</u> Declaration Declaration of Jayne Risk, # <u>5</u> Exhibit 1, # <u>6</u> Exhibit 2, # <u>7</u> Exhibit 3, # <u>8</u> Exhibit 4, # <u>9</u> Exhibit 5, # <u>10</u> Exhibit 6, # <u>11</u> Exhibit 7, # <u>12</u> Exhibit 8, # <u>13</u> Exhibit 9, # <u>14</u> Exhibit 10, # <u>15</u> Exhibit 11,

		# <u>16</u> Exhibit 12, # <u>17</u> Exhibit 13, # <u>18</u> Exhibit 14, # <u>19</u> Exhibit 15, # <u>20</u> Exhibit 16)(RISK, JAYNE) Modified on 1/17/2017 (tjd). (Entered: 01/16/2017)
01/16/2017	<u>19</u>	MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM <i>MOTION TO COMPEL ARBITRATION OR, IN THE ALTERNATIVE, TO DISMISS COMPLAINT</i> filed by GLAXOSMITHKLINE LLC, GLAXOSMITHKLINE PLC.Memorandum, Declaration, Exhibits, Certificate of Service. (Attachments: # <u>1</u> Memorandum, # <u>2</u> Text of Proposed Order, # <u>3</u> Certificate of Service, # <u>4</u> Declaration Declaration of Jayne Risk, # <u>5</u> Exhibit 1, # <u>6</u> Exhibit 2, # <u>7</u> Exhibit 3, # <u>8</u> Exhibit 4, # <u>9</u> Exhibit 5, # <u>10</u> Exhibit 6, # <u>11</u> Exhibit 7, # <u>12</u> Exhibit 8, # <u>13</u> Exhibit 9, # <u>14</u> Exhibit 10, # <u>15</u> Exhibit 11, # <u>16</u> Exhibit 12, # <u>17</u> Exhibit 13, # <u>18</u> Exhibit 14, # <u>19</u> Exhibit 15, # <u>20</u> Exhibit 16)(RISK, JAYNE) (Entered: 01/16/2017)
02/17/2017	<u>20</u>	STIPULATION AND ORDER IS DENIED. SIGNED BY HONORABLE NITZA I QUINONES ALEJANDRO ON 2/16/17. 2/16/17 ENTERED AND COPIES MAILED, E-MAILED.(ti, ) Modified on 2/17/2017 (ti, ). (Entered: 02/17/2017)
02/22/2017	<u>21</u>	STIPULATION for Extension of Time to File Response/Reply filed by CHINAWHYS COMPANY LTD, PETER HUMPHREY, YU YINGZENG.Brief. (Attachments: # <u>1</u> Text of Proposed Order)(ZACH, JOHN) Modified on 2/23/2017 (afm, ). (FILED IN ERROR, FORWARDED TO JUDGE FOR APPROVAL) (Entered: 02/22/2017)
02/22/2017	<u>22</u>	STIPULATION AND ORDER THAT PLAINTIFFS' DEADLINE TO OPPOSE THE MOTION IS 3/3/2017, DEFENDANTS' REPLY DEADLINE IS 3/31/2017. SIGNED BY HONORABLE NITZA I QUINONES ALEJANDRO ON 2/22/2017. 2/22/2017 ENTERED AND COPIES MAILED AND E-MAILED.(sg, ) (Entered: 02/22/2017)
03/03/2017	<u>23</u>	Memorandum in Opposition re <u>19</u> MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM <i>MOTION TO COMPEL ARBITRATION OR, IN THE ALTERNATIVE, TO DISMISS COMPLAINT</i> filed by CHINAWHYS COMPANY LTD, PETER HUMPHREY, YU YINGZENG. (Attachments: # <u>1</u> Text of Proposed Order (Proposed Order Denying Defendants' Motion to Dismiss the Complaint))(ZACH, JOHN) Modified on 3/6/2017 (tjd). (Entered: 03/03/2017)
03/03/2017	<u>24</u>	Declaration re <u>19</u> MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM <i>MOTION TO COMPEL ARBITRATION OR, IN THE ALTERNATIVE, TO DISMISS COMPLAINT</i> Declaration of John T. Zach in Opposition to Defendants' Motion to Compel Arbitration, or, in the Alternative, to Dismiss the Complaint by CHINAWHYS COMPANY LTD, PETER HUMPHREY, YU YINGZENG. (Attachments: # <u>1</u> Exhibit A, # <u>2</u> Exhibit B, # <u>3</u> Exhibit C, # <u>4</u> Exhibit D, # <u>5</u> Exhibit E, # <u>6</u> Exhibit F)(ZACH, JOHN) (Entered: 03/03/2017)
03/31/2017	<u>25</u>	REPLY Memorandum in Support re <u>19</u> MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM <i>MOTION TO COMPEL ARBITRATION OR, IN THE ALTERNATIVE, TO DISMISS COMPLAINT</i> filed by

		GLAXOSMITHKLINE LLC, GLAXOSMITHKLINE PLC. Certificate of Service. (Attachments: # <u>1</u> Certificate of Service)(RISK, JAYNE) Modified on 3/31/2017 (lisad, ). (Entered: 03/31/2017)
08/02/2017	<u>26</u>	NOTICE by GLAXOSMITHKLINE LLC, GLAXOSMITHKLINE PLC <i>Notice of Supplemental Authority</i> (Attachments: # <u>1</u> Supplemental Authority -- Bristol-Myers Squibb Decision, # <u>2</u> Certificate of Service)(HELLER, NATHAN) (Entered: 08/02/2017)
09/29/2017	<u>27</u>	MEMORANDUM AND/OR OPINION SIGNED BY HONORABLE NITZA I QUINONES ALEJANDRO ON 9/29/17. 9/29/17 ENTERED AND COPIES E-MAILED.(ti, ) (Entered: 09/29/2017)
09/29/2017	<u>28</u>	ORDER THAT, FOR THE REASONS SET FORTH IN THE ACCOMPANYING MEMORANDUM OPINION FILED ON THIS DAY, THAT DEFENDANTS' MOTION TO DISMISS IS GRANTED, AND PLAINTIFFS' COMPLAINT <u>1</u> IS DISMISSED. SIGNED BY HONORABLE NITZA I QUINONES ALEJANDRO ON 9/29/17. 9/29/17 ENTERED AND COPIES E-MAILED.(ti, ) (Entered: 09/29/2017)
10/16/2017	<u>29</u>	NOTICE OF APPEAL re <u>27</u> Memorandum/Opinion, <u>28</u> Memorandum/Opinion Order <i>together with Certificate of Service</i> by CHINAWHYS COMPANY LTD, PETER HUMPHREY, YU YINGZENG. Filing fee \$ 505, receipt number 167390. Copies to Judge, Clerk USCA, Appeals Clerk and CHINAWHYS COMPANY LTD, PETER HUMPHREY, YU YINGZENG. (ti, ) Modified on 10/17/2017 (ti, ). Modified on 10/17/2017 (lisad, ). (Entered: 10/17/2017)
10/23/2017	<u>30</u>	NOTICE of Docketing Record on Appeal from USCA re <u>29</u> Notice of Appeal, filed by PETER HUMPHREY, YU YINGZENG, CHINAWHYS COMPANY LTD. USCA Case Number 17-3285 (dmc, ) (Entered: 10/24/2017)

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

---

PETER HUMPHREY, YU YINGZENG, and  
CHINAWHYS COMPANY LTD,

Plaintiffs,

v.

GLAXOSMITHKLINE PLC and  
GLAXOSMITHKLINE LLC,

Defendants.

---

Civil Action No.: 2:16-CV-5924

**DEFENDANTS’ MOTION TO COMPEL ARBITRATION, OR, IN THE  
ALTERNATIVE, MOTION TO DISMISS THE COMPLAINT**

Defendants GlaxoSmithKline plc (“**GSK PLC**”) and GlaxoSmithKline LLC (“**GSK LLC**”) (collectively, “**GSK Defendants**”), through their counsel, move to compel arbitration of the entirety of Plaintiffs’ Complaint pursuant to a written agreement providing for arbitration before the China International Economic and Trade Arbitration Commission (“**CIETAC**”).

In the alternative, GSK PLC, a British entity with no ties to the United States, moves to dismiss the Complaint for lack of personal jurisdiction. GSK PLC does not maintain systematic and continuous contacts with either the United States or the Commonwealth of Pennsylvania, and did not perform any action directed here giving rise to the alleged claims. The Court therefore lacks personal jurisdiction over GSK PLC.

The GSK Defendants additionally move to dismiss the Complaint for failure to state a claim and for failure to join an indispensable party. Plaintiffs’ Complaint pleads no facts giving rise to alleged racketeering, conspiracy, or emotional distress claims against the GSK

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

---

PETER HUMPHREY, YU YINGZENG, and  
CHINAWHYS COMPANY LTD,

Plaintiffs,

v.

GLAXOSMITHKLINE PLC and  
GLAXOSMITHKLINE LLC,

Defendants.

---

Civil Action No.: 2:16-CV-5924

**DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR  
MOTION TO COMPEL ARBITRATION, OR, IN THE  
ALTERNATIVE, MOTION TO DISMISS THE COMPLAINT**

Defendants GlaxoSmithKline plc (“**GSK PLC**”) and GlaxoSmithKline LLC (“**GSK LLC**”) (collectively, “**GSK Defendants**”), through their counsel, submit the following memorandum in support of their motion to compel arbitration, or in the alternative, motion to dismiss the complaint for lack of personal jurisdiction, failure to state a claim upon which relief can be granted, failure to join an indispensable party, and failure to bring a timely action under Pennsylvania law.

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## I. SUMMARY OF ARGUMENT

Plaintiffs' complaint ("**Complaint**") suffers from multiple overriding defects, any one of which is alone fatal to their claims. Most notably, Plaintiffs commenced this action notwithstanding the fact that their claims are governed by a binding agreement ("**Consultancy Agreement**") requiring that the parties "*submit the dispute to the China International Economic and Trade Arbitration Commission*" ("**CIETAC**") in Beijing for arbitration." (See Ex. 1, Consultancy Agreement, at § 11.) The Court should enforce that arbitration clause, and should stay all proceedings pending conclusion of the CIETAC arbitration, at which point judgment should be entered in accordance with any arbitral award.

Notwithstanding the mandatory referral to arbitration, Plaintiffs' claims fail on the merits and, as to GSK PLC, on jurisdictional grounds. Plaintiffs attempt to mount racketeering, fraud, conspiracy and emotional distress claims against the GSK Defendants by stringing together allegations that, on their face, do not pertain to, and were not committed by either defendant. Plaintiffs have identified no basis to impute any alleged activities to the GSK Defendants, nor have they identified any link between GSK PLC, (a United Kingdom ("**U.K.**") entity formed under British law) and the United States ("**U.S.**") that would support exercising personal jurisdiction over GSK PLC.

Lastly, Plaintiffs have failed to join GlaxoSmithKline (China) Investment Co. Ltd. ("**GSK China**"), the signatory to the Consultancy Agreement containing the binding arbitration provision and an indispensable party to this lawsuit. A full and fair adjudication on the merits of this matter cannot occur without GSK China's participation.

Accordingly, the Court should grant the GSK Defendants' motion to compel arbitration and require Plaintiffs to proceed with their claims before the CIETAC. Alternatively, the Court should dismiss the claims against GSK PLC for lack of jurisdiction, and should otherwise

dismiss the entirety of Plaintiffs' Complaint for failure to state a claim upon which relief can be granted, failure to join an indispensable party, and failure to bring a timely action under Pennsylvania law.

## II. PRELIMINARY STATEMENT

This lawsuit is at its core a dispute between Peter Humphrey ("**Humphrey**"), Yu Yingzeng ("**Yu**") and ChinaWhys Company Ltd. ("**ChinaWhys Ltd**") (collectively, "**Plaintiffs**") against a non-party/separate GSK entity, GSK China, regarding a Consultancy Agreement signed in China, for services to be provided in China which is governed by Chinese law and subject to a binding arbitration provision; but the lawsuit has been improperly commenced in a U.S. federal court by Plaintiffs against two unrelated GSK entities, GSK PLC and GSK LLC (the GSK Defendants), which have no connection to the Consultancy Agreement or to the dispute. Plaintiffs' Complaint violates an enforceable and binding agreement to arbitrate, and thus requires dismissal of this action. Further, Plaintiffs' effort to bring a China-based dispute in this forum creates insurmountable jurisdictional and standing hurdles and leaves them unable to articulate plausible claims against the entities they chose to sue in this Court.

Plaintiffs' allegations arise out of services provided to GSK China pursuant to an April 25, 2013 Consultancy Agreement entered into between GSK China and ChinaWhys (Shanghai) Consulting Co. Ltd. ("**ChinaWhys (Shanghai)**"). (*See* Ex. 1, Consultancy Agreement & App'x A.)<sup>1</sup> Under this agreement, GSK China retained ChinaWhys for due diligence and investigation services following a security incident at a GSK China executive's apartment in March 2013. GSK China engaged ChinaWhys to investigate the circumstances of

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<sup>1</sup> As explained in greater detail in Section III(C), all references herein to ChinaWhys ("**ChinaWhys**") will refer collectively to the named plaintiff in this lawsuit, ChinaWhys Ltd, as well as ChinaWhys (Beijing), ChinaWhys (Shanghai), ChinaWhys (Hong Kong), and all other consulting companies co-founded and co-owned by Humphrey and Yu. *See, infra*, Section III(C).

the security incident and the potential involvement of a former employee (Vivian Shi (“**Shi**”)). Under Section 11 of the Consultancy Agreement, the parties agreed that any disputes that arose would be governed by the laws of China, and would be submitted to CIETAC. (*See* Ex. 1, Consultancy Agreement § 11.)

Specifically, Section 11 of the Consultancy Agreement, entitled “Governing Law and Dispute Resolution,” provides:

This Agreement shall be governed in all respects by the laws of the People’s Republic of China. *All disputes arising out of or in connection with this Agreement shall be settled through friendly consultation between both parties. In case no settlement can be reached, either Party may submit the dispute to the China International Economic and Trade Arbitration Commission (“CIETAC”) in Beijing for arbitration in accordance with the CIETAC rules of arbitration then in effect. The arbitration award shall be final and binding* on the Parties.”

(*Id.*)

Section 1.6 of the Consultancy Agreement further provides:

[ChinaWhys] shall carry out the Consulting Services *always in a lawful and ethical manner*. The term ‘ethical’ used in the policy means: *in compliance with all laws, regulations, legal and professional guidelines*, and in a manner not likely to result in harm to GSK’s reputation or image.”

(*Id.* at § 1.6.)

On or around July 10, 2013, ChinaWhys’ co-founders and co-managers, husband/wife Humphrey and Yu, were detained by the Shanghai police on suspicion of violating Chinese laws relating to the purchase of personal information and data. They were arrested on August 16, 2013 and charged with trafficking in private records of Chinese individuals. (*See* Ex. 2.) Plaintiffs now attempt to blame their personal and business injuries arising from their arrest, conviction and incarceration on GSK, alleging that it was somehow their performance of services for GSK that caused their arrest.

Plaintiffs fail to disclose in their Complaint that in 2013, less than two months before he and Yu were arrested by the Chinese authorities, Humphrey published an article explicitly criticizing the Chinese government for newly promulgated rules and regulations restricting access to personal information. (*See* Ex. 3.)<sup>2</sup> In that article, Humphrey described recent crackdowns in May 2012 and January 2013 by the Chinese government, and new regulations promulgated in February 2013, which further enforced laws regarding access to and dissemination of personal information, noting specifically that this had led to “more than 1,000 local investigators and their alleged sources . . . [being] detained.” (*Id.*) As evidenced by the article, Humphrey was well aware of Chinese legal restrictions governing the use of personal information, and the risks that he and other investigators faced if they failed to comply with these restrictions. Simply put, Humphrey failed to heed his own warnings. The GSK Defendants had nothing to do with Humphrey’s article or this failure to comply with Chinese law. To the contrary, the Consultancy Agreement specifically required ChinaWhys to conduct its work under the engagement in accordance with Chinese law. (*See* Ex. 1, Consultancy Agreement at § 1.6.) Humphrey, Yu and ChinaWhys, upon their own initiative and despite knowledge of the risks, chose to disregard this requirement.

Plaintiffs instead attempt to spin a tale of a global racketeering enterprise and conspiracy involving GSK PLC and GSK LLC, claiming that their mistreatment in China in 2013 was somehow related to the marketing of pharmaceutical products in the U.S. in 1999 and to the resolution between GSK LLC and the U.S. Health & Human Services Department

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<sup>2</sup> P. Humphrey, The Fraud Examiner, “How Fraud Investigation Just Got Harder in China: Exploring the Impact of China’s Clampdown on Public Records” (May 2013), *available at* <http://www.acte.com/fraud-examiner.aspx?id=4294978054>.

(“**2012 U.S. Settlement**”);<sup>3</sup> this in order to insinuate a U.S. nexus and attempt to implicate the U.S. Racketeer Influenced and Corrupt Organizations Act (“**RICO**”), stretching RICO well beyond the breaking point of rational interpretation. The subject matter involved in the 2012 U.S. Settlement ended in 2010 (and much of it earlier than that), many years before ChinaWhys had involvement with GSK China or entered into the Consultancy Agreement in April 2013. Likewise, Plaintiffs’ allegations that a subsequent 2013 investigation in China and related attention from U.S. regulators are part of a common scheme are also baseless. The China and U.S. investigations involved conduct unrelated to the Humphrey and Yu claims and were fully resolved by GSK China and the Chinese government on September 19, 2014 (“**2014 China Judgment**”),<sup>4</sup> and by GSK PLC and the U.S. Securities and Exchange Commission (“**U.S. SEC**”) on September 30, 2016 (“**2016 U.S. Settlement**”).<sup>5</sup> Plaintiffs’

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<sup>3</sup> On July 2, 2012, GSK LLC agreed to plead guilty and to pay \$3 billion to resolve criminal and civil liabilities arising from the promotion of certain prescription drugs, failure to report certain safety data, and civil liabilities for alleged false price reporting practices. (*See* Ex. 4, Press Release, U.S. Dep’t of Justice, GlaxoSmithKline to Plead Guilty to Pay \$3 Billion to resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), Ex. 5, Corporate Integrity Agreement, Office of Inspector General of the Dep’t of Health and Human Services and GlaxoSmithKline LLC (July 2, 2012).) This criminal and civil liability arose from conduct that occurred in, and was directed towards, the U.S. between 1994 and 2010. The settlement resolved claims relating to activities in the U.S. for Paxil, Wellbutrin, Avandia, Advair and other products, as well as allegations of false price reporting under the U.S. Federal Medicaid Rebate Program. (*Id.*) The 2012 U.S. Settlement does not relate to any matters in China. (*Id.*)

<sup>4</sup> On September 19, 2014, the Changsha Intermediate People’s Court in Hunan Province, China entered the 2014 China Judgment against GSK China for approximately \$489.5 million in relation to conduct implicating Articles 67 and 164 of the Criminal Law of the People’s Republic of China, which prohibit offering money or property to non-governmental Chinese personnel in order to obtain improper commercial gains. (*See* Ex. 6, Press Release, GlaxoSmithKline, GSK China Investigation Outcome (Sept. 19, 2014).) Neither GSK LLC nor GSK PLC were parties to, or the subjects of, the 2014 China Judgment. (*Id.*)

<sup>5</sup> On September 30, 2016, the U.S. SEC and GSK PLC entered into the 2016 U.S. Settlement, in a civil resolution of the recordkeeping and internal controls provisions of the U.S. Foreign Corrupt Practices Act of 1977. (*See* Ex. 7, Press Release, GlaxoSmithKline Pays \$20 Million Penalty to Settle FCPA Violations (Sept. 30, 2016), Ex. 8, *In the Matter of GlaxoSmithKline plc*, A.P. No. 3-17606, Order (Sept. 30, 2016).) The resolution mentions specific violations relating to conduct by GSK PLC’s indirect subsidiary, GSK China, between 2010 and June 2013. (*Id.*) GSK PLC was named as a party, not based on any conduct related to the settlement but solely because its American Depositary Receipts are registered with the U.S. SEC under Section 12(b) of the Securities Exchange Act and trade on the New York Stock Exchange under the symbol “GSK,” and its consolidated books and records and internal controls, which relate to the activities of all wholly-owned subsidiaries, were rendered inaccurate or revealed to be insufficient as a result of conduct by GSK China. Neither GSK LLC nor GSK China were parties to the 2016 U.S. Settlement. Nor was any conduct in China by GSK PLC itself at issue in the settlement. The 2016

allegation that these unrelated events were part of a common scheme not to comply with laws at issue with respect to the convictions of Humphrey and Yu in China or to “cover up” the activities of GSK in China is baseless on its face.

Finally, Plaintiffs’ decision not to name GSK China as a defendant in an action involving the very Consultancy Agreement which they entered into with GSK China can be no accident. Plaintiffs intentionally omitted this indispensable party in an effort to circumvent the mandatory arbitration provision of the Consultancy Agreement and to avoid the jurisdictional obstacles that would foreclose a lawsuit in the U.S. against the only GSK entity with which they actually interacted.

### **III. FACTUAL BACKGROUND**

Plaintiffs’ Complaint alleges six causes of action: (1) violations of 18 U.S.C. § 1962(c) (Racketeering), (2) violations of 18 U.S.C. § 1962(d) (Conspiracy), (3) fraud, (4) intentional infliction of emotional distress, (5) negligent infliction of emotional distress and (6) civil conspiracy. (*See e.g.*, Compl. ¶¶ 121-137, 137-149, 150-156, 157-163, 164-170, 171-175.)

#### **A. Consultancy Agreement**

Although Plaintiffs referred only in a nuanced way to the Consultancy Agreement in the Complaint, all of their claims necessarily arise from services that ChinaWhys contracted in April 2013 to provide GSK China. (Comp. ¶¶ 49-90.) GSK China had no other dealings with Plaintiffs. The GSK Defendants were not parties to the Consultancy Agreement. (*See* Ex. 1, Consultancy Agreement.)

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U.S. Settlement was based on the same conduct implicated in the 2014 China Judgment; the U.S. SEC declined to impose any additional disgorgement beyond that already captured by the Chinese judgment. GSK LLC, including its employees, agents and contractors, was not a participant or connected in any way to the matters that occurred in China, and thus it was not a party to the 2016 U.S. Settlement.

Section 11 of the Consultancy Agreement mandates arbitration of all disputes arising out of or in connection with the agreement as follows:

This Agreement *shall be governed in all respects* by the laws of the Peoples Republic of China. All disputes arising out of or in connection to this Agreement shall be settled through friendly consultation between both parties. In case no settlement can be reached, either party may submit the dispute to the China International Economic and Trade Commission (“CIETAC”) in Beijing for arbitration in accordance with the CIETAC rules of arbitration then in effect. *The arbitration award shall be final and binding on the parties.*

(See Ex. 1, Consultancy Agreement § 11.)

#### **B. GSK China: Party to Consultancy Agreement**

The only GSK-related party to the Consultancy Agreement was GSK China, a wholly-owned indirect subsidiary of GSK PLC. (See Ex. 9, GSK China Decl., at ¶ 3.) GSK China, however, is not named as a party in the Complaint. GSK China is incorporated under Chinese law. (*Id.*) Notwithstanding the corporate relationship between GSK China and GSK PLC, they maintain all the formalities of separate corporations. (*Id.* at ¶ 4.) GSK China maintains books and records, payrolls, bank accounts and a board of directors independently of GSK PLC. (*Id.*) Moreover, GSK China and GSK PLC are separately and adequately capitalized. (*Id.*) GSK China’s principal place of business is in Shanghai, China. (*Id.* at ¶ 5.) It has never conducted commercial operations in the United States or the Commonwealth of Pennsylvania. (*Id.* at ¶ 6.)

On behalf of GSK China, the Consultancy Agreement was approved by Mark Reilly (“**Reilly**”), then-general manager of GSK China. (See Ex. 1.) Reilly’s responsibilities and job function related solely to GSK China’s business in China. (See Ex. 9, GSK China Decl. at ¶ 8.) GSK China was the GSK entity which executed the Consultancy Agreement entered into between GSK China and ChinaWhys through the ChinaWhys alter egos ChinaWhys (Shanghai) Consulting Co. Ltd. and ChinaWhys Co. Ltd. (*Id.* at ¶ 7.)

According to the Complaint, ChinaWhys interacted with the following GSK-affiliated employees during the negotiations, execution and performance of the Consultancy Agreement: Mark Reilly (General Manager, GSK China), Maggie Zheng (Administrative Assistant to Mark Reilly, GSK China), April Zhao (former Legal Director, GSK China), Jennifer Huang (former Senior Counsel, Legal Department, GSK China R&D Company Ltd), Leslie Chang (Head of Business Development and Office of the General Manager, GSK China), Brian Cahill (“**Cahill**”) (former GSK Pte. Ltd (Singapore) Senior Vice President and General Counsel, Asia), and June Soon (“**Soon**”) (Executive Secretary, GSK Pte. Ltd (Singapore)). (*See e.g.*, Compl. ¶¶ 50, 64, 70, 79, 80, 82, 83, 84, 86, 87, 88, 89.) Cahill and his assistant Soon were both based in Singapore, and all of the other above-referenced GSK employees were based in China. (*See* Ex. 9, GSK China Decl. at ¶¶ 8-11.) None of those individuals were employed by either of the GSK Defendants.

### **C. ChinaWhys Entities: Party to Consultancy Agreement**

Although ChinaWhys Ltd is the entity named in the Complaint as a plaintiff, ChinaWhys (Shanghai) was the specific party to the Consultancy Agreement. (*See* Ex. 1.) According to the Complaint, ChinaWhys Ltd was co-founded by Humphrey and Yu. (*See* Compl. ¶¶ 6-7.) The ChinaWhys website indicates that Humphrey incorporated ChinaWhys Ltd in Hong Kong in 2003. (*See* Ex. 10.) As ChinaWhys’ managing director, Humphrey signed the Consultancy Agreement and Appendix A, which was incorporated by reference on behalf of ChinaWhys (Shanghai). (*See* Ex. 1.)

The Complaint does not identify ChinaWhys Ltd’s place of incorporation or principal place of business. (*See* Compl. ¶¶ 6-8.) A website purporting to be that of ChinaWhys, however, identifies Humphrey and Yu as the co-founders of a consulting company referred to only

as “ChinaWhys,” and states that this entity is incorporated in Hong Kong. (*See* Exs. 10-12).<sup>6</sup> Notably, the website also refers to the company’s motto as: “Connecting the dots . . . for businesses in China.”

According to its website, ChinaWhys is a “China-based professional-services consultancy providing specialized risk mitigation solutions, consulting and investigation services to corporate clients in sensitive matters across Greater China and Asia.” (*See* Ex. 10 ChinaWhys Website.) The website also represents to the public that ChinaWhys provides “regular advice to businesses on risk management and ha[s] conducted services in China for large, medium and small multinationals, professional services firms, NGOs, chambers of commerce and high wealth individuals, and further that it offers a “cost-effective practice centered on Greater China.” (*Id.*)

#### **D. GlaxoSmithKline plc**

Although it is not a party to the Consultancy Agreement or responsible for the services rendered by ChinaWhys, GSK PLC is named as a defendant in the Complaint. (*See* Ex. 13, GSK PLC Decl. ¶ 17.) None of the GSK employees referred to in the Complaint were employed by GSK PLC. (*Id.* ¶ 18.)

GSK PLC is a public limited company organized under the laws of England and Wales, with its principal place of business at 980 Great West Road, Brentford, Middlesex TW8 9GS, England. (*Id.* at ¶ 3.) GSK PLC was created and exists solely for the purpose of holding the stock of its subsidiaries, through several layers of wholly owned subsidiaries. (*Id.* at ¶ 4.) GSK PLC is not incorporated under the laws of the Commonwealth of Pennsylvania. (*Id.* at ¶ 3.) GSK PLC has never conducted commercial operations anywhere in the world, including the United States and the Commonwealth of Pennsylvania. (*Id.* at ¶ 5.) GSK PLC has never designed,

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<sup>6</sup> *See generally* ChinaWhys Company Website, available at [chinawhys.com/index.htm](http://chinawhys.com/index.htm).

developed, manufactured, marketed or sold any products or services anywhere in the world, including the United States and the Commonwealth of Pennsylvania. (*Id.* at ¶ 6.) GSK PLC is not and has never been a direct shareholder of GSK LLC. (*Id.* at ¶ 7.) GSK PLC and GSK LLC maintain all the formalities of separate corporations. (*Id.* at ¶ 8.) GSK PLC and GSK LLC do not maintain common books and records, payrolls, bank accounts, or boards of directors. GSK LLC and GSK PLC are separately and adequately capitalized. (*Id.*) Similarly, GSK PLC and GSK China also maintain all of the formalities of separate corporations. (*Id.* at ¶ 9.)

#### **E. GlaxoSmithKline LLC**

GSK LLC likewise was not a party to the Consultancy Agreement (including all appendices entered into between GSK China and ChinaWhys) nor was it responsible for the services rendered by ChinaWhys. (*See* Ex. 14, GlaxoSmithKline LLC Decl., at ¶ 9.) GSK LLC is a limited liability company organized in the state of Delaware, with corporate operations in Research Triangle Park, North Carolina and Philadelphia, Pennsylvania. (*Id.* at ¶ 3.) GSK LLC is an indirect wholly-owned subsidiary of GSK PLC. (*Id.* at ¶ 4.) GSK LLC and GSK PLC maintain all the formalities of separate corporations. (*Id.* at ¶ 5.) GSK LLC maintains books and records, payrolls, bank accounts, and a board of directors independently of GSK PLC. GSK LLC and GSK PLC are separately and adequately capitalized. (*Id.*)

At all relevant times (at least from 2001 through present), GSK LLC is not, and has not been, a direct or indirect shareholder of GSK China. (*Id.* at ¶ 6.) At least from 2013 through present, GSK LLC has had no commercial operations in China. (*Id.* at ¶ 7.) None of the GSK-affiliated individuals who were referred to in the Complaint were employed by GSK LLC or otherwise performed services on behalf of, or directed towards, GSK LLC during the relevant time period (April through July 2013). (*Id.* at ¶ 8.) At least from 2013 through the present, GSK LLC has had no commercial operations in China. (*Id.* at ¶ 7.)

The relationships between the relevant ChinaWhys and GSK entities is summarized by the diagram on the following page.

**F. Arrest/Conviction of Humphrey and Yu**

Humphrey and Yu were convicted of the charges against them. (*See*

Ex. 15.) Following his arrest, in a CCTV report, Humphrey was quoted in the media as saying, “We sometimes use illegal methods to obtain personal information. I very much regret doing this, and I want to apologize to the Chinese government.” (*See* Ex. 16.)

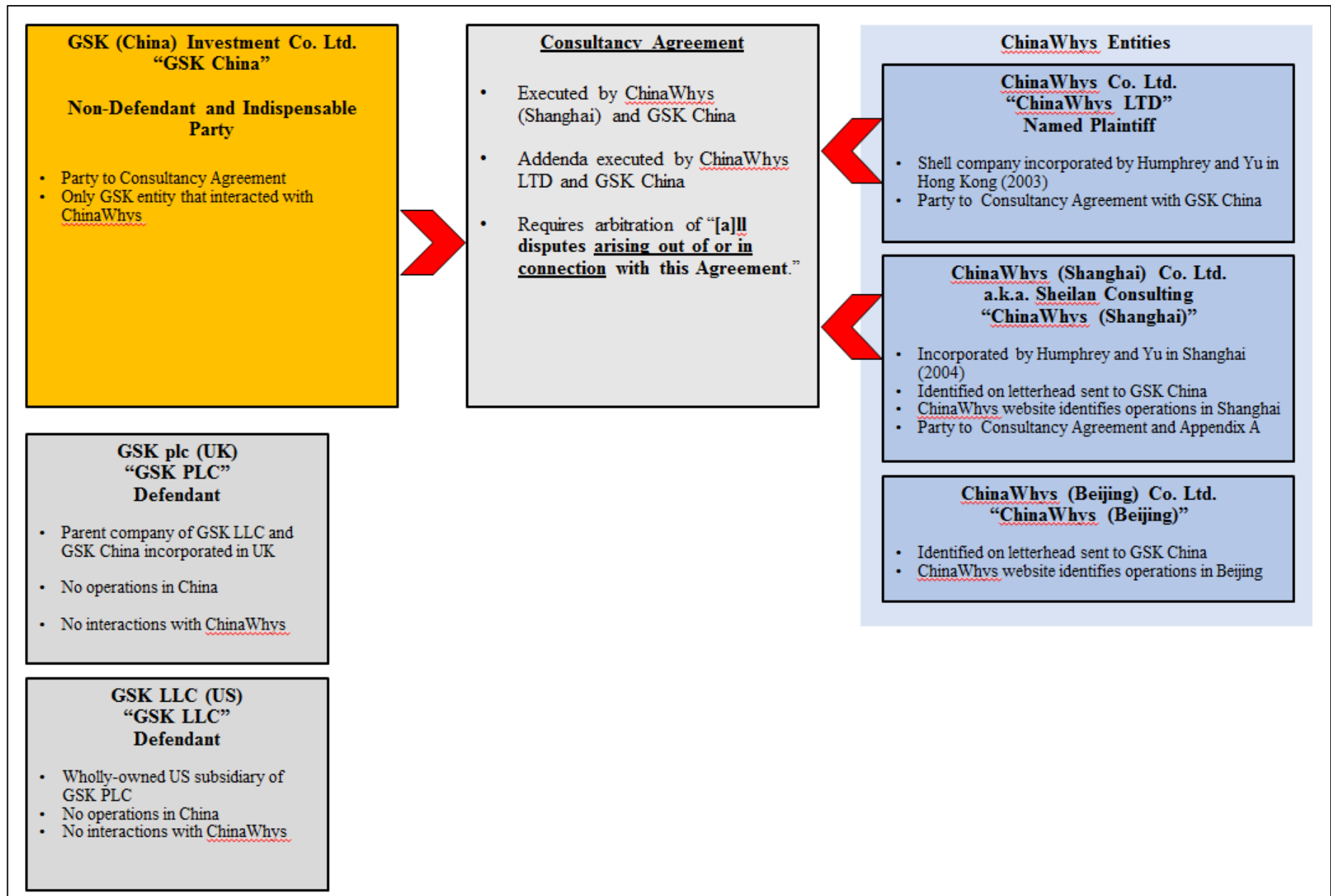
Humphrey was sentenced to two-and-one-half years in prison, and fined £20,000. While Yu was sentenced to two years in prison, and fined £15,000. (Compl. ¶ 97;

Ex. 15 CCTV Article (Aug. 27, 2013).) Humphrey and Yu were released from prison in or around June 9, 2015, and thereafter departed China on June 17, 2015. (Compl. ¶¶ 105-06.)

**IV. ARGUMENT**

**A. The Court Should Compel Arbitration Of The Present Dispute Under The Federal Arbitration Act And The United Nations Convention On The Recognition And Enforcement Of Foreign Arbitral Awards, And Should Stay All Proceedings Pending Completion Of Arbitration**

The arbitration of disputes in this matter is governed by the Federal Arbitration Act (“FAA”). The FAA embodies “a strong federal policy in favor of resolving disputes through arbitration.” *Invista S.A.R.L. v. Rhodia, S.A.*, 625 F.3d 75, 83-84 (3d Cir. 2010). A “written provision in a ... commercial contract showing an agreement to settle disputes by arbitration ‘shall be valid, irrevocable, and enforceable, save upon such grounds as exist in law or equity for the revocation of any contract.’” *Just B. Method, LLC v. BSCPS, LP*, No. 14-1516, 2014 WL 5285634, at \*4 (E.D. Pa. Oct. 14, 2014) (Alejandro, J.) (*quoting Century Indem. Co. v. Certain Underwriters at Lloyd’s London*, 584 F.3d 513, 522 (3d Cir. 2009) and 9 U.S.C. § 2)).



**Figure 1.** Relationship of Relevant GSK and ChinaWhys Entities.

The FAA's second chapter implements the United Nations New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards ("**New York Convention**"), which provides for enforcement and recognition of arbitration provisions in international commercial contracts. Under that chapter, a court will enforce such provisions "if they arise from commercial, legal relationships, such as commercial contracts, except when those relationships are entirely between United States citizens and otherwise are domestic in nature."<sup>7</sup> *Century Indem. Co.*, 584 F.3d at 523 (citing 9 U.S.C. § 202). Together, the FAA and the New York Convention recognize an "emphatic federal policy in favor of arbitral dispute resolution." *Mitsubishi Motors Corp. v. Soler Chrysler-Plymouth, Inc.*, 473 U.S. 614, 631 (1985); see also *Shearson/American Exp., Inc. v. McMahon*, 472 U.S. 220, 226 (1987) ("The Arbitration Act thus establishes a federal policy favoring arbitration, requiring that "we rigorously enforce agreements to arbitrate.") (internal citations and quotations omitted).

When a court is requested to compel arbitration under the New York Convention, it must consider the following four factors, adopted by the U.S. Court of Appeals for the Third Circuit in *Standard Bent Glass Corp. v. Glassrobots Oy*, 333 F.3d 440 (3d Cir. 2003):

- (1) Is there "an agreement in writing to arbitrate the subject of the dispute"?
- (2) "Does the agreement provide for arbitration in the territory of a signatory of the Convention?"
- (3) "Does the agreement arise out of a legal relationship, whether contractual or not, which is considered as commercial?"
- (4) "Is a party to the agreement not an American citizen, or does the commercial relationship have some reasonable relation with one or more foreign states."

*Standard Bent Glass*, 333 F.3d at 449 & n.13; accord *Century Indem. Co.*, 584 F.3d at 523 n.8.

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<sup>7</sup> "The domestic FAA applies to actions brought under the New York Convention to the extent that the two are not in conflict." See 9 U.S.C. § 208.

“If the answers are all in the affirmative, the court must order arbitration unless it determines the agreement is null and void.” *Standard Bent Glass*, 333 F.3d at 449 & n.13.

1. All Four Of The *Standard Bent Glass* Factors Favor Arbitration.

i. *A Written Agreement Exists Between The Parties To Arbitrate The Subject Of The Dispute.*

To obtain an order compelling arbitration under the New York Convention, a party must show the existence of a written agreement to arbitrate the subject of the dispute. *Standard Bent Glass Corp.*, 333 F.3d at 449. Here, Section 11 of the Consultancy Agreement broadly states that “[a]ll disputes arising out of or in connection with” the agreement are subject to arbitration. (Ex. 1 Consultancy Agreement § 11.) Clauses using this same or similar formulations give rise to “a presumption of arbitrability” under which arbitration “*should not be denied unless it may be said with positive assurance that the arbitration clause is not susceptible of an interpretation that covers the asserted dispute.*” *Moses H. Cone Mem. Hosp. v. Mercury Constr. Corp.*, 460 U.S. 1, 24 (1983) (emphasis added); *see also Hinnant v. Am. Ingenuity, LLC*, 554 F. Supp. 2d 576, 587 (E.D. Pa. 2008) (holding that a clause providing for arbitration of “all disputes in connection with this contract” created a broad presumption of arbitrability).

Plaintiffs cannot meet that exacting standard. Any claims Plaintiffs allege must ultimately arise out of or in connection to the engagement. According to the Complaint, Plaintiffs were retained by GSK China following a meeting with company representatives. (See Compl. ¶ 50.) That meeting produced the Consultancy Agreement, which provided for due diligence and investigative services including inquiries into Shi (See Ex. 1, Consultancy Agreement § 1.1.) Plaintiffs’ efforts to carry out their duties under the Consultancy Agreement are the only activities that they could have performed in relation to *any* GSK entity. To wit, Plaintiffs’ own allegations link their arrest to GSK. (See Compl. ¶ 91.) As such, according to

their own allegations, any claims Plaintiffs could assert would necessarily arise out of or relate to the Consultancy Agreement.

Plaintiffs' election to style their claims under RICO and state tort law does not abrogate the arbitrability of those claims. As the U.S. Court of Appeals for the Third Circuit has recognized: "If the allegations underlying the claims touch matters covered by [an arbitration clause in a contract], then those claims must be arbitrated, whatever the legal labels attached to them." *Brayman Const. Corp. v. Home Ins. Co.*, 319 F.3d 622, 626 (3d Cir. 2003) (alteration in original) (quoting *Genesco, Inc. v. T. Kakiuchi & Co.*, 815 F.2d 840, 846 (2d Cir. 1987)). In fact, the *Genesco* case upon which the Third Circuit relied in reaching that conclusion expressly found that RICO claims fell within the scope of a broad arbitration provision because "[t]he wire, mail, and transportation fraud allegations which form the predicate acts of [the] RICO claim all derive from the parties' transactions under the [applicable] agreements." *Genesco*, 815 F.2d at 848. The same is true here. As set forth in the Complaint, the various mail and wire frauds allegedly perpetrated by the GSK Defendants were purportedly made to "induce [Plaintiffs] to carry out an investigation that served GSK's political goals." (*See* Compl. ¶ 127.) An undisclosed number of those communications were allegedly made "with Humphrey, Yu, and other ChinaWhys employees" for the purpose of "inducing them to carry out an [allegedly] contrived investigation" for the GSK Defendants. (*See* Compl. ¶ 128(c).) The present dispute therefore "aris[es] out of or in connection with" that Consultancy Agreement and is subject to its broad arbitration provision. (*See* Ex. 1, Consultancy Agreement § 11.)

The arbitration clause is mandatory; the use of the word "may" does not render it permissive or discretionary. As one court has explained:

[T]his Court does not distinguish between the use of the term "may" or "shall" in the arbitration context. Instead, we generally recognize that

the language permitting either party to demand arbitration operates to require the parties to submit to arbitration, as it clearly demonstrates that the parties contemplated the use of arbitration proceedings as the forum for resolution of disputes.

*D & H Distrib. Co. v. Nat'l Union Fire Ins.*, 817 A.2d 1164, 1169 (Pa. Super. Ct. 2003). This Court too has “rejected ... argument[s] that the use of the word ‘may’ automatically renders an arbitration clause permissive.” Under the prevailing interpretation, “arbitration clauses using the word ‘may’ have been held to compel mandatory arbitration on the grounds that such language merely manifests the parties’ intent that arbitration be obligatory if either party so chooses.” *Brown v. City of Philadelphia*, No. 10-2687, 2010 WL 4484630, at \*5 (E.D. Pa. Nov. 9, 2010); *see also American Italian Pasta Co. v. Austin Co.*, 914 F.2d 1103, 1104 (8th Cir. 1990); *Sidorek v. Chesapeake Appalachia LLC*, 3:13-CV-0208, 2014 WL 1218893, at \*3 (M.D. Pa. Mar. 24, 2014).

The same rationale applies here. The provision in the Consultancy Agreement that “either Party may submit the dispute” to arbitration evinces an intent that a demand for arbitration will be binding once made by either party. *Brown*, 2010 WL 4484630, at \*5; *Sidorek*, 2014 WL 1218893, at \*3. The mandatory nature of the “friendly consultation” requirement bolsters that conclusion. There would be little reason for the parties to agree to a mandatory conciliation process, but immediately thereafter provide a purely optional arbitration provision that neither party could compel the other to follow. Were that the case, the arbitration provision would be of no effect, as it would merely suggest that the dispute could be submitted to arbitration if the parties agreed to do so after the dispute arose—an avenue that they could pursue without an arbitration clause. *See United States v. Bankers Ins. Co.*, 245 F.3d 315, 321 (4th Cir. 2001) (holding that interpreting “may” as permissive in the arbitration context “would render the arbitration provision meaningless for all practical purposes[,] since parties could always

voluntarily submit [ ] to arbitration.”) (alterations in original; internal quotations omitted). The far more likely scenario is that, “by using the word ‘may,’ both parties were given the power to enforce the arbitration clause.” *In re Winstar Commc’ns*, 335 B.R. 556, 563 (Bankr. D. Del. 2005); *see also United Steelworkers of Am., v. Ft. Pitt Steel Casting*, 598 F.2d 1273, 1279 n.18 (3d Cir. 1979) (finding that the district court did not err in holding that grievance procedures in a collective bargaining agreement were “mandatory despite language in the collective bargaining agreement that the parties ‘may’ invoke those procedures.”).

The present dispute therefore falls within the scope of the Consultancy Agreement’s mandatory arbitration provision. The first *Standard Bent Glass* factor should be answered in the affirmative.

ii. *The Arbitration Agreement Provides For Arbitration In The Territory Of A Signatory State.*

To obtain an order compelling arbitration under the New York Convention, a party must next demonstrate that the agreement at issue provides for arbitration in a signatory state. *Standard Bent Glass Corp.*, 333 F.3d at 449 n.13. Both the U.S. and China are signatories to the Convention. *See* New York Arbitration Convention, Contracting States, available at <https://www.newyorkconvention.org/countries> (last visited January 16, 2017). The Consultancy Agreement specifically provides for application of the laws of the Peoples Republic of China and arbitration before “[CIETAC] in Beijing.” (*See* Ex. 1, Consultancy Agreement § 11.)

The second *Standard Bent Glass* factor is therefore answered in the affirmative.

iii. *The Consultancy Agreement Sets Forth A Legal Relationship That Is Considered Commercial.*

Next, the Court must consider whether the agreement at issue “arise[s] out of a legal relationship ... which is considered as commercial.” *Standard Bent Glass Corp.*, 333 F.3d at 449

n.13. In the arbitration context, courts have broadly construed the term “commercial” to apply to any matter that “‘has a connection with commerce, whether or not that commerce has a nexus with the United States.’” *Belize Social Dev. Ltd. v. Gov’t of Belize*, 794 F.3d 99, 104 (D.C. Cir. 2015) (quoting Restatement (Third) of U.S. Law of Int’l Comm. Arbitration § 1-1 cmt. e); accord *Island Territory of Curacao v. Solitron Devices, Inc.*, 356 F. Supp. 1, 13 (S.D.N.Y. 1973) (“[I]t seems clear that the full scope of ‘commerce’ and ‘foreign commerce,’ as those terms have been broadly interpreted, is available for arbitral agreements and awards.”).

The Consultancy Agreement is a written document setting forth a legal relationship that addresses a commercial matter. It contains provisions under which Plaintiffs would provide professional services to GSK China, outlines the parameters of their work, and provides the terms and conditions under which they were to be paid. It is the quintessential service contract between a service provider and a client. (See Ex. 1, Consultancy Agreement §§ 1.1-1.6, 3.1-3.4.) As such, it represents a commercial arrangement between its signatories and touches on a matter “considered as commercial” for purposes of the New York Convention. *Standard Bent Glass Corp.*, 333 F.3d at 449 n.13. The third *Standard Bent Glass* factor is therefore answered in the affirmative.

iv. *A Party To The Consultancy Agreement Is Not An American Citizen, Or It Has A Reasonable Relationship With A Foreign State.*

Lastly, the Court must determine whether a non-American is a signatory to the agreement at issue, or whether there is “some reasonable relation with one or more foreign states.” *Standard Bent Glass Corp.*, 333 F.3d at 449 n.13. Although only one of those characteristics is needed to compel arbitration, the Consultancy Agreement features both. *Id.* Neither party to the Consultancy Agreement is an American citizen. GSK China is incorporated under Chinese law, maintains its principal place of business in Shanghai, and operates exclusively in China. (See Ex.

9, GSK China Decl. ¶¶ 3-4.) ChinaWhys is formed under the law of Hong Kong. (*See* Ex. 10.) More importantly, the meeting at which Plaintiffs were retained by GSK China occurred in China, the investigative services provided by Plaintiffs under the Consultancy Agreement were performed in China, and all of the material events giving rise to this action occurred in and were focused on conduct in China. The Consultancy Agreement not only has a reasonable relationship with a foreign state (China), but in fact its only relationship is with China. The final *Standard Bent Glass* factor is therefore answered in the affirmative.

Accordingly, because all four of the *Standard Bent Glass* factors are met, the Court should issue an order compelling arbitration in accordance with the FAA and the New York Convention.

2. No Grounds Exist To Refuse Arbitration Under The Consultancy Agreement.

Once a dispute falls within the scope of the New York Convention, the Court should grant a motion to compel unless it finds that the agreement is “null and void.” *Standard Bent Glass*, 333 F.3d at 449. No such grounds for such a finding exist here.

i. Plaintiffs Have Not Made An Attempt To Invalidate The Consultancy Agreement.

Plaintiffs do not mention the arbitration requirement in their Complaint, much less raise a particularized allegation as to that provision. GSK PLC and GSK LLC are entitled to invoke the arbitration provision of the Consultancy Agreement.

Even though GSK PLC and GSK LLC are not direct signatories to the Consultancy Agreement, they are nonetheless entitled to invoke its arbitration provision. An arbitration clause may be enforced by a nonsignatory if a “close relationship” exists between the entities involved and if “the claims were intimately founded in and intertwined with the underlying contract obligations.” *E.I. DuPont de Nemours*, 269 F.3d at 199. In essence, when a claim arises

by or against one member of a corporate family by virtue of a related company's contract, the non-signatory may invoke any arbitration provision in that contract. *Id.*; see also *Bannett v. Hankin*, 304 F. Supp. 2d 354, 359 (E.D. Pa. 2004) (“[N]onsignatories to an arbitration agreement have standing to compel arbitration against a signatory and the signatory is estopped from avoiding arbitration with a nonsignatory when the issues which the nonsignatory wants to resolve are intertwined with the agreement that the signatory signed.”).

Here, Plaintiffs' claims against GSK PLC and GSK LLC allegedly arose while Plaintiffs were carrying out their investigatory obligations under the Consultancy Agreement with GSK China. (Compl. ¶¶ 49-70.) Those claims are “intimately founded in and intertwined with” the Consultancy Agreement such that GSK PLC and GLK LLC assumed standing to enforce the arbitration provision of that contract. *E.I. DuPont de Nemours*, 269 F.3d at 199. Plaintiffs must, therefore, bring their claims arising from the Consultancy Agreement in an arbitration tribunal regardless of which GSK corporate entities they attempt to pursue as defendants.

- ii. *The Court May Require Humphrey, Yu, And ChinaWhys To Arbitrate Their Claims Due To Their Affiliation With ChinaWhys (Shanghai), Which Is The Signatory To The Consultancy Agreement.*

The Court may compel the Plaintiffs to arbitrate even though the Consultancy Agreement was signed only by Humphrey on behalf of ChinaWhys (Shanghai). “Because arbitration is a creature of contract law, when asked to enforce an arbitration agreement against a non-signatory to the contract, a district court must determine whether the non-signatory individual ‘is bound by that agreement under traditional principles of contract and agency law.’” *Just B. Method*, 2014 WL 5285634, at \*7 (quoting *E.I. DuPont de Nemours & Co. v. Rhone Poulenc Fiber & Resin Intermediaries, S.A.S.*, 269 F.3d 187, 194-95 (3d Cir. 2001)). Under those principles, a party may be compelled to arbitrate under principles of (1) incorporation by reference, (2) assumption

of contractual rights or obligations, (3) agency, (4) alter ego, and (5) estoppel. *Allstate Settlement Corp. v. Rapid Settlements, Ltd.*, 559 F.3d 164, 170 (3d Cir. 2009).

(1) *The Consultancy Agreement Binds Humphrey And Yu Under Principles Of Agency And Estoppel.*

Under agency principles, when a contract signatory retains another individual or entity as an agent to carry out its contractual obligations, claims accruing as a result of the agent's conduct are subject to any arbitration provision contained in the contract. *Pritzker v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 7 F.3d 1110, 1121 (3d Cir. 1993). The Complaint alleges that Humphrey and Yu are co-founders of ChinaWhys (Shanghai), the signatory to the Consultancy Agreement, and that both Humphrey and Yu were acting in their capacity as principals and agents of ChinaWhys at all times relevant to their claims. (*See* Compl. ¶¶ 6, 7.) The Complaint further alleges that Humphrey was introduced to GSK China by a former ChinaWhys client based on the specialized consulting services ChinaWhys provides. (*Id.* ¶ 49.) The Complaint confirms as well that Humphrey and Yu are “employees” of ChinaWhys, and alleges that the GSK Defendants dictated “Humphrey and Yu’s mission” in carrying out the Consultancy Agreement. (*Id.* ¶¶ 63, 128(c) (referring to “Humphrey, Yu, and other ChinaWhys employees”).) The investigation performed by Humphrey and Yu is the same as that described in the scope of work outlined in ChinaWhys’ project proposal. (*See* Ex. 1, Consultancy Agreement App’x A.) Accordingly, Humphrey and Yu were acting as agents of ChinaWhys with regard to the facts alleged in the Complaint, and they are bound by the arbitration clause in the Consultancy Agreement.

Humphrey and Yu are also bound by the arbitration clause in the Consultancy Agreement under an equitable estoppel theory. A non-signatory to a contract may be bound by a contractual arbitration provision “if the non-signatory exploits the agreement containing the arbitration

clause despite never having signed the agreement.” *E.I. DuPont de Nemours*, 269 F.3d at 200. This Court has recognized that, when an individual litigant “[s]eeks to reap the full benefits of [an] Agreement” executed by an entity of which the litigant is a principal, the individual may be compelled to arbitrate claims arising under that agreement. *See Just B Method*, 2014 WL 5285634, at \*9. Here Humphrey and Yu sought to reap the benefits for the work that was performed in China for the purpose of carrying out their obligations under the Consultancy Agreement. The Court should, therefore, compel Humphrey and Yu to arbitrate in accordance with that agreement.

(2) *The Consultancy Agreement Binds ChinaWhys Under Principles Of Alter Ego, Agency, And Assumption Of Contract Rights.*

Under alter ego principles, one corporate entity may be bound by an arbitration clause in a contract signed by an affiliated company when the two entities have so comingled their operations that they function as a single enterprise. *Aluminium Bahrain B.S.C. v. Dahdaleh*, 17 F. Supp. 3d 461, 471 (W.D. Pa. 2014). Similarly, under principles of assumption, one entity may be bound by an arbitration clause if its “subsequent conduct indicates that it is assuming the obligation to arbitrate.” *Invista S.A.R.L.*, 625 F.3d at 85 (internal quotations omitted). Here, Humphrey’s and Yu’s conduct in China was allegedly performed to satisfy ChinaWhys (Shanghai)’s obligations under the Consultancy Agreement, despite the fact that the Complaint attributes that conduct to ChinaWhys and alleges that Humphrey and Yu performed their investigation on ChinaWhys’ behalf. (Comp. ¶¶ 49-70.) ChinaWhys was operating to fulfill ChinaWhys (Shanghai)’s obligation to “initiate inquiries into [Shi] and her contacts.” (See Ex. 1, Consultancy Agreement App’x A, at 4.) The actions of Humphrey and Yu are thus attributable to ChinaWhys (Shanghai), the contract signatory, because the two ChinaWhys entities functioned as a single enterprise using the same personnel.

Alternatively, the Consultancy Agreement binds ChinaWhys under an agency theory because ChinaWhys, through its employees, was acting as the agent of ChinaWhys (Shanghai) to fulfill contractual obligation of the latter entity. “Because a principal is bound under the terms of a valid arbitration clause, its agents, employees, and representatives are also covered under the terms of such agreements.” *Pritzker*, 7 F.3d at 1121.

Moreover, ChinaWhys’ conduct reflects an intent to be bound regardless of any alter ego or agency relationship. ChinaWhys directed its personnel into China for the specific purpose of furthering the relationship between GSK China and ChinaWhys (Shanghai) created by the Consultancy Agreement. By acting on behalf of ChinaWhys (Shanghai) to meet its contractual duties, ChinaWhys manifested its intent to be bound by the contract from which those duties arose. *See Thomson-CSF, S.A. v. Am. Arb. Ass’n*, 64 F.3d 773, 777 (2d Cir. 1995) (“In the absence of a signature, a party may be bound by an arbitration clause if its subsequent conduct indicates that it is assuming the obligation to arbitrate.”).

The Court should find that ChinaWhys is bound by the arbitration provisions of the Consultancy Agreement.

iii. *Arbitration Remains Proper Notwithstanding That Humphrey And Yu Are No Longer In China.*

The Court may compel arbitration notwithstanding that Humphrey and Yu were allegedly “deported from China on June 17, 2015” and are no longer physically present or resident in China. (*See* Compl. ¶ 106.) A contract such as the Consultancy Agreement incorporates into its terms the law existing at the time of its formation. *See DePaul v. Kauffman*, 272 A.2d 500, 506 (Pa. 1971). In this case, the chosen law governing the agreement is the law of China and the chosen forum is CIETAC. (*See* Ex. 1, Consultancy Agreement at § 11.) CIETAC rules provide that “[a] party may be represented by its authorized Chinese and/or foreign representative(s) in

handling matters relating to the arbitration,” even if the party cannot or chooses not to attend the proceeding in person. *See* CIETAC Arb. R. art. 22.<sup>8</sup> By assenting to the arbitration provision in the Consultancy Agreement, Plaintiffs agreed to use and rely upon CIETAC procedures, including those allowing a representative to conduct the arbitration on the party’s behalf. Accordingly, the fact that Humphrey and Yu are not in China should not preclude the Court from granting a motion to compel arbitration in accordance with the Consultancy Agreement.

**B. The Court Must Dismiss All Claims Against GSK PLC For Lack Of Personal Jurisdiction**

1. The Court Cannot Assert General Jurisdiction Over GSK PLC

In order for the Court to assert general personal jurisdiction over a foreign corporation, the corporation’s affiliations with the forum state must be “so constant and pervasive” that it is essentially “at home” there. *Daimler AG v. Bauman*, 134 S. Ct. 746, 751 (2014). Except for “an exceptional case” such as a temporary relocation of a corporate headquarters, a corporation is “at home” only in its formal place of incorporation and its principal place of business. *Id.* at 761.

GSK PLC is a public limited company with its principal place of business in Middlesex, United Kingdom. (*See* Ex. 13, GSK PLC Decl. ¶ 3.) GSK PLC’s sole purpose is to act as a holding company for its global operations through a series of intermediate holding companies responsible for its various divisions. (*Id.* ¶ 4.) GSK PLC has no operations, no sales, no employees, and no other activities in the U.S. (*Id.* ¶ 5.) Accordingly, under *Daimler*, the Court has no basis to assert general jurisdiction over GSK PLC.

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<sup>8</sup> *See also Jiangsu Changlong Chemicals, Co. v. Burlington Bio-Med. & Sci. Corp.*, 399 F. Supp. 2d 165, 169 (E.D.N.Y. 2005) (confirming award over due process objection that company representatives were prevented from obtaining necessary visas to attend Chinese arbitration, when counsel had appeared at arbitration on defendant’s behalf).

## 2. The Court Cannot Assert Specific Jurisdiction Over GSK PLC

Specific jurisdiction focuses on “minimum contacts” between a non-resident defendant and the forum with respect to the claims asserted against it. *Dollar Sav. Bank v. First Sec. Bank of Utah*, 746 F.2d 208, 211-12 (3d Cir. 1984). First, the defendant must have “purposefully directed [its] activities” at the forum. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (quotation marks omitted). Second, the litigation must “arise out of or relate to” at least one of those forum-related activities. *Helicopteros Nacionales de Colombia v. Hall*, 466 U.S. 408, 418 n.8 (1984); *Grimes v. Vitalink Comms. Corp.*, 17 F.3d 1553, 1559 (3d Cir. 1994). Finally, jurisdiction must otherwise “comport with ‘fair play and substantial justice.’” *Burger King*, 471 U.S. at 476.

Thus, for a controversy to “arise out of” or be “related to” the forum state, a corporation’s “suit-related conduct must create a substantial connection with the forum State.” *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014) (emphasis added). Contacts unrelated to the alleged claims will not support jurisdiction. *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 299 (1980) (“[F]inancial benefits accruing to the defendant from a collateral relation to the forum State will not support jurisdiction if they do not stem from a constitutionally cognizable contact with that State.”).

Here, the analysis is straightforward, as the Complaint fails to allege that GSK PLC had any contacts with the forum related to Plaintiffs’ claims. Nor, in fact, have Plaintiffs alleged suit-related conduct in the forum with respect to any of the GSK Defendants. In the absence of any allegations that GSK PLC acted in Pennsylvania with respect to Plaintiffs’ claims, it cannot be subject to this Court’s personal jurisdiction, and all claims against GSK PLC should be dismissed.

**C. The Court Lacks Subject Matter Jurisdiction Over Plaintiffs’ State-Law Claims (Counts III, IV and V)**

Aside from RICO (18 U.S.C. § 1964), Plaintiffs allege only diversity under 28 U.S.C. § 1332 as the basis for this Court’s subject matter jurisdiction.

However, Plaintiffs cannot rely upon diversity jurisdiction to provide this Court with subject-matter jurisdiction over their non-RICO claims. (*Cf.* Compl. ¶¶ 7, 12 (alleging American citizenship of Yu and relying on diversity statute as a basis for jurisdiction).) Under 28 U.S.C. § 1332, a court may assert diversity jurisdiction over suits between “citizens of different states” (U.S.C. § 1332(a)(1)), “citizens of a State and citizens or subjects of a foreign state” (28 U.S.C. § 1332(a)(2)), and “citizens of different States and in which citizens or subjects of a foreign state are additional parties” (28 U.S.C. § 1332(a)(3)). None of these provisions applies here:

In order to be a citizen of a State within the meaning of the diversity statute, a natural person must be both a citizen of the U.S. *and be domiciled within the State*. An American citizen domiciled abroad, while being a citizen of the U.S. is, of course, not domiciled in a particular state, and therefore such a person is ‘stateless’ for purposes of diversity jurisdiction. Thus, American citizens living abroad . . . are neither ‘citizens of a State,’ *see* 28 U.S.C. § 1332(a)(1), nor ‘citizens or subjects of a foreign state,’ *see id.* § 1332(a)(2).

*Swiger v. Allegheny Energy, Inc.*, 540 F.3d 179, 183–84 (3d Cir. 2008).

Yu is not domiciled in the U.S., and is not a citizen of a state within the meaning of the diversity statute. Accordingly, the Court lacks subject-matter jurisdiction over Plaintiffs’ state-law claims (Counts III, IV and V).

**D. The Complaint Fails To State A Claim Upon Which Relief May Be Granted**

Rule 8(a)(2), which applies to all complaints, requires a “short and plain statement” to “show[] that [the plaintiff] is entitled to relief.” Fed. R. Civ. P. 8(a)(2). To meet this requirement, the complaint must be “plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2007). This means a plaintiff must plead sufficient facts to permit the court “to draw the reasonable inference

that the defendant is liable for the misconduct alleged.” *Santiago v. Warminster Township*, 629 F.3d 121, 128 (3d Cir. 2010) (*quoting Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 262 n.27 (3d Cir. 2010)). “[R]ecitals of the elements of a cause of action, supported by mere conclusory statements,” are insufficient. *Id.* (*quoting Iqbal*, 556 U.S. at 667).

Additionally, claims grounded in fraud must be plead with particularity under Fed. R. Civ. P. 9(b). Pursuant to Rule 9(b), a plaintiff averring a claim in fraud must specify “the who, what, when and where details of the alleged fraud.” *District 1199P Health and Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 508, 527 (D. N.J. 2011). Further:

To determine the sufficiency of a complaint in the Third Circuit, a court must take three steps: First, the court must take note of the elements a plaintiff must plead to state a claim. Second, the court should identify allegations that, because they are no more than conclusions, are not entitled to the assumption of truth. Third, where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief.

*Santiago*, 629 F. 3d at 130.

A review of each of Plaintiffs’ six causes of action reveals that none give rise to an entitlement for relief. As such, the Court should thus dismiss the Complaint.

#### 1. Plaintiffs Sued The Wrong Entities

Plaintiffs cannot meet either the Rule 8 or heightened Rule 9(b) pleading standards as to any claims, for one simple reason: Plaintiffs have named the wrong entities.<sup>9</sup> The named GSK Defendants in the Complaint are (1) GSK PLC, and (2) one of GSK PLC’s subsidiaries, GSK LLC. (*See* Compl. ¶¶ 10, 11.) However, as set forth above in Sections III(D)-(E), neither GSK PLC nor GSK LLC is alleged to have committed any conduct actually directed towards Plaintiffs. Rather, every single individual alleged to have interacted with the Plaintiffs is

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<sup>9</sup> As set forth more fully in Section III, Plaintiffs’ alleged claims arise from the Consultancy Agreement, a contract to which neither GSK PLC nor GSK LLC are signatories.

associated with one of two entirely different GSK subsidiaries: either GSK China, GSK (China) R&D Co. Ltd. (“**GSK China (R&D)**”) or GlaxoSmithKline Pte. Ltd. (“**GSK Singapore**”).

Specifically, as alleged in Plaintiffs’ Complaint:

- The “GSK officials” at the April 15, 2013 meeting at which Plaintiffs were “asked to conduct a background investigation of Shi” (Compl. ¶¶ 49-63) were:
  - Reilly, the General Manager of GSK China; (Compl. ¶ 50.)
  - Zhao, Legal Counsel to GSK China; and (Compl. ¶ 50.)
  - Cahill, an employee of GSK Singapore. (Compl. ¶ 50; *see also* Ex. 9, GSK China Decl. ¶ 10.)
- The employees from whom Humphrey sought additional information (Zhao and Reilly) were Legal Counsel and CEO of GSK China, respectively; (Compl. ¶ 64.)
- The location to which ChinaWhys employee Silvia Feng allegedly traveled to obtain information was the Shanghai office of GSK China; (Compl. ¶ 65.)
- The individuals to whom Humphrey sent a background investigation report (Zhao, Huang, and Cahill) were employees of GSK China, GSK China (R&D) and GSK Singapore; (Compl. ¶ 70.)
- The individuals who requested follow-up investigation work by Humphrey—which Humphrey declined to perform—were legal counsel to GSK China (R&D) (Huang) and Head of Business Development for GSK China (Chang); (Compl. ¶¶ 79, 82-85.)
- The individual who allegedly forwarded Humphrey and a ChinaWhys manager copies of the whistleblower emails was an employee of GSK Singapore (Soon); and (Compl. ¶ 80.)
- Subsequent alleged July 2013 contacts involved only Reilly and his personal assistant (Zheng). (Compl. ¶¶ 86, 89.)

Further, none of this alleged conduct by employees of GSK China and GSK Singapore, even if proven tortious, could be imputed to either of the GSK Defendants in this case. “As a general rule, a parent corporation, like any stockholder, is not normally liable for the wrongful acts or contractual obligations of a subsidiary . . . simply because the parent wholly owns the subsidiary.” *Jean Anderson Hierarchy of Agents v. Allstate Life Ins. Co.*, 2 F. Supp. 2d 688, 691

(E.D. Pa. 1998). Under Pennsylvania law, there is “a strong presumption . . . against piercing the corporate veil. *Germain v. Wisniewski*, No. 15-1297, 2016 WL 4158994, at \*2 (W.D. Pa. Aug. 5, 2016) (quoting *Lumax Indus., Inc. v. Autman*, 669 A.2d 893, 895 (Pa. 1985)). The “formulaic recitation of the elements . . . for piercing the corporate veil” is insufficient to survive a motion to dismiss. *Essex Ins. Co. v. Miles*, No. 10-3598, 2010 WL 5069871, at \*3 (E.D. Pa. Dec. 3, 2010) (allegations that “on information and belief” corporate entity’s owners failed to observe corporate formalities, intermingled funds, used corporate property for personal expenses, left the entity grossly undercapitalized, and used the entity as a façade or alter ego did not meet the *Twombly* pleading standard).

Here, Plaintiffs have not even attempted to allege the elements of a veil piercing claim, making only a bare, conclusory allegation that GSK PLC “had the right to and did exercise control over the actions of” GSK China. (*See* Compl. ¶ 10.) This is insufficient. The allegation that a company is “entirely dominated, operated, and controlled” by another is a “threadbare and conclusory” allegation insufficient to state a claim for veil piercing. *Sunlight Elec. Contracting Co. v. Turchi*, No. 08-5834, 2011 WL 4086077, at \* 17-18 (E.D. Pa. Sept 13, 2011). Where the only allegations against a parent and sister corporation are as to their corporate relationship to the entity that committed the wrongful acts, the complaint must be dismissed as to those defendants. *Jean Anderson Hierarchy of Agents v. Allstate Life Ins. Co.*, 2 F. Supp. 2d at 692; *see also Davis v. Wells Fargo U.S. Bank Nat’l Ass’n*, No. 14-07014, 2015 WL 3555301, at \*4-5 (E.D. Pa. June 8, 2015) (dismissing complaint against corporate parent company for acts committed by its subsidiary).

Simply put, Plaintiffs have sued the wrong corporate entities, and the Complaint should be dismissed in its entirety on this basis alone.

2. Plaintiffs Fail To State A Claim For Violation of 18 U.S.C. § 1962(c) or (d)

Plaintiffs lack standing to bring RICO claims because they do not allege facts supporting a causal link between the GSK Defendants' actions and Plaintiffs' alleged RICO losses. Second, Plaintiffs do not plausibly allege a "pattern" of racketeering activity as required for violation of 18 U.S.C. § 1962(c). Finally, Plaintiffs do not plausibly allege that GSK PLC and GSK LLC entered into an agreement to participate in the affairs of a RICO enterprise, as required under 18 U.S.C. § 1962(d).

i. Plaintiffs Fail To Allege Violation Of § 1962 Proximately Caused Their Damages

Plaintiffs' RICO claims must be dismissed because Plaintiffs do not plausibly allege that a violation of § 1962 proximately caused their damages. Under 18 U.S.C. § 1964(c), a private plaintiff may only bring a civil suit if he or she is "injured in his business or property by reason of a violation of section 1962." 18 U.S.C. § 1964(c). The U.S. Supreme Court has read this requirement strictly: plaintiffs may only recover damages actually and proximately caused by a defendant's RICO violation. *Holmes v. Secs. Investor Prot. Corp.*, 503 U.S. 258, 268-69 (1992). RICO proximate cause is defined by directness: where injury "rests on the independent actions of third and even fourth parties," there is no proximate cause. *Hemi Grp., LLC v. City of New York, N.Y.*, 599 U.S. 1, 15 (2010). Foreseeability—in contrast to many states' common law formulation of proximate cause—is irrelevant. *Id.* It does not matter whether injuries caused by the independent actions of a third party are foreseeable, intended or even desired. *Id.* Rather, the RICO proximate cause requirement "ensures that there are no independent variables that could account for a plaintiff's injuries." *District 1099P*, 784 F. Supp. 2d at 525 (dismissing RICO claims because, among other reasons, defendants' fraudulent statements were not the sole cause of Plaintiffs' injuries).

Here, it was not the alleged actions by GSK LLC, GSK PLC or even GSK China or GSK Singapore that directly caused Plaintiffs' injuries. Rather, Plaintiffs allege their injuries were directly caused by third parties: the Chinese criminal justice system—the Chinese police (Compl. ¶¶ 91-92), prosecutors (Compl. ¶¶ 92-97), and Chinese detention center employees and prison officials (Compl. ¶¶ 99-103). In fact, assuming that Plaintiffs' allegations are true, the actions of the Chinese criminal justice system are arguably fourth party acts, as Plaintiffs allege their "prosecution was procured at the behest of Shi, seeking revenge against them. . . ." (Compl. ¶ 97). Indeed, Plaintiffs do not contest that they committed the violations of law, dating back over many years, that were the cause of their punishment in China.

Plaintiffs make *no* factual allegations that *any* activity by GSK LLC had a causal impact on Plaintiffs, either direct or indirect. Plaintiffs' allegations that GSK PLC's putative refusal to disclose information to British diplomats prolonged Humphrey's and Yu's incarceration is unavailing, as Plaintiffs do not (and cannot) plausibly allege that GSK PLC's alleged statements or refusal to provide information were the *sole* reason that the British government was unsuccessful in securing their early release. (Compl. ¶ 115.)

As alleged, Plaintiffs' injuries simply cannot be considered the "direct" result of action by the GSK Defendants: assuming that Plaintiffs' allegations are true, Plaintiffs' conduct in the investigation incurred the wrath of Shi; Shi purportedly procured Plaintiffs' arrest and prosecution by the Chinese criminal justice system; and inhumane treatment by Chinese authorities injured Plaintiffs. (Compl. ¶¶ 91-104.) Because it was independent actors responding to Plaintiffs' own violations of Chinese law who directly caused Plaintiffs' alleged harm, even accepting their allegations at face value, Plaintiffs cannot claim that their injuries were proximately caused by Defendants.

ii. Plaintiffs Fail To Allege A Pattern Of RICO Activity

“A plaintiff bringing a substantive RICO claim under § 1962(c) must allege ‘(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity.’” *Hlista v. Safeguard Properties, LLC*, 649 F. App’x 217, 221 (3d Cir. 2016) (quoting *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 362 (3d Cir. 2010)). The requirements of § 1962(c) “must be established as to each individual defendant.” *Craig Outdoor Advertising, Inc. v. Viacom Outdoor, Inc.*, 528 F.3d 1001 (8th Cir. 2008).

As the U.S. Supreme Court explained in *H.J. Inc. v. Northwestern Bell Tel. Co.*, a series of racketeering activities only constitutes a RICO “pattern” where the activities are (1) related to each other and (2) amount to or otherwise constitute a threat of continuing racketeering activity. 492 U.S. 229, 240 (1989). Activities are related when they “have the same or similar purposes, results, participants, victims, or methods of commission, or otherwise are interrelated by distinguishing characteristics and are not isolated events.” *Id.* Plaintiffs’ claims regarding the alleged “Drug Bribery and Promotion Enterprise” fail to meet that standard by any definition.

Plaintiffs allege three distinct subsets of conduct within the purported enterprise: (1) the 2012 U.S. Settlement (Compl. ¶¶ 15-22); (2) GSK China’s “Corruption in China” (Compl. ¶¶ 71-78, 116-120); and (3) GSK China’s engagement of Plaintiffs to “conduct a background investigation of [Vivian] Shi” (Compl. ¶¶ 49-70, 79-90). Contrary to the *H.J., Inc.* requirement that the elements of a pattern be “related,” Plaintiffs’ own allegations demonstrate that the purported elements of the alleged RICO enterprise are in fact, entirely unrelated, and do not involve the same or even similar results, participants, victims, or methods of commission. Indeed, timing alone demonstrates the disjointed nature of Plaintiffs’ allegations: there are no allegations involving GSK LLC after the 2012 U.S. Settlement, while GSK China employees are not alleged to have made contact with Plaintiffs prior to mid-2013. (Compl. ¶¶ 15, 50.)

In an attempt to tie these disparate acts together, Plaintiffs argue, without alleging any facts, that each “portion of the enterprise” is connected to the others because all have the “common purpose to maximize and protect GSK profits.” (Compl. ¶ 123.) This bald assertion is insufficient to tie together Plaintiff’s unrelated and disparate allegations.

In *Bonavitacola Elec. Contractor, Inc. v. Boro Developers, Inc.*, plaintiffs alleged conduct over the course of a decade through which the defendant electrical contractor bid for and won several public works projects, in each instance by fraudulently promising to comply with prevailing wage laws and subsequently submitting false certified payroll reports. 87 F. App’x 227, 232 (3d Cir. 2003). Plaintiffs alleged this series of events met the relatedness requirement by virtue of their “similar purpose of procuring electrical construction contracts.” *Id.* The Third Circuit disagreed and affirmed dismissal of these claims, holding that an alleged similar purpose “is not an allegation of common plan.” *Id.* Plaintiffs’ efforts to shoehorn conduct by GSK LLC and GSK PLC into the complaint under the guise of a common purpose of “maximizing profits” similarly fails.

Nor does Plaintiffs’ allegation that they were hired as part of an effort to “cover-up” the alleged enterprise render this series of communications “related” to the activity alleged against GSK LLC. *See The Knit With v. Knitting Fever, Inc.*, 625 F. App’x 27, 38 (3d Cir. 2015) (while a scheme to cover up activity may have “some connection” to that activity, this connection alone is “not sufficient to make two conspiracies part of the same pattern of racketeering”). Indeed, hiring Plaintiffs to conduct a background report into a former employee could not plausibly be part of an effort to “cover-up” any GSK LLC activities, which had already been disclosed to the public as part of its settlement almost a full year before GSK China and GSK Singapore employees allegedly first contacted Plaintiffs. (*See* Exs. 4-5.)

Nor can the “portion” of the alleged racketeering activity purportedly directed towards Plaintiffs stand as a “pattern” on its own. “Predicate acts extending over a few weeks or months and threatening no future criminal conduct do not satisfy” the continuity requirement of *H.J. Inc.* 492 U.S. at 242. All alleged interaction between Plaintiffs and employees of GSK China and GSK Singapore took place during the course of three months. When the alleged pattern of activity takes place over such a short timeframe, and when it is not related to an open-ended pattern of racketeering activity, a claim under 18 U.S.C. § 1962(c) fails. *See Jordan v. Berman*, 792 F. Supp. 380, 385-86 (E.D. Pa. 1992) *partially overruled on other grounds*, 20 F.3d 1250 (3d Cir. 1994) (citing examples of Third Circuit cases holding that “twelve months or less is not a ‘substantial’ period for RICO continuity purposes.”); *Walther v. Patel*, No. 10-706, 2011 WL 382752 at n.105 (E.D. Pa. Feb 4, 2011) (same).

iii. *Plaintiffs’ 1962(d) Claim Fails Because Plaintiffs Have Not Alleged an Agreement*

To plead a cause of action for RICO conspiracy (§ 1962(d)), the complaint “must set forth factual allegations that indicate (1) the period of the conspiracy, (2) its intended purpose, (3) the specific actions taken by the conspirators in furtherance of the conspiracy, (4) agreement to commit predicate acts, and (5) knowledge that the acts agreed upon formed part of a pattern of racketeering activity.” *Ferguson v. Moeller*, No. 2:16-CV-41, 2016 WL 1106609, at \*8 (W.D. Pa. March 22, 2016) (citing *Glessner v. Kenny*, 952 F.2d 702, 714 (3d Cir. 1991)). Plaintiffs must allege facts showing that “each defendant objectively manifested an agreement to participate, directly or indirectly, in the affairs of a RICO enterprise.” *Id.* Plaintiffs’ conclusory allegations do not meet this requirement.

Plaintiffs allege that “[t]he corporate defendants conspired with, inter alia, Mark Reilly and others to promote the red herring investigation of Vivian Shi . . .” (Compl. ¶¶ 140, 141.)

However, Plaintiffs offer no allegations whatsoever to support this statement. They make no claim that any employee of GSK LLC or GSK PLC knew that GSK China and GSK Singapore employees had the objective of “promoting [a] red herring investigation,” let alone that GSK LLC and GSK PLC agreed to further this alleged endeavor for the purpose of “suppress[ing] evidence of GSK’s fraud and bribery in China.” *See Id.* Mere conclusory statements such as these, with “no specific averments regarding . . . agreement to join an alleged conspiracy as to each defendant,” are insufficient to state a cognizable § 1962(d) claim. *Ferguson*, 2016 WL 1106609, at \*9.<sup>10</sup>

3. Plaintiffs’ Claim For Fraud Fails Because Neither GSK Defendant Made Any Allegedly Misleading Statements To Plaintiffs

Plaintiffs’ claim for fraud also fails because the wrong defendants once again were named. Plaintiffs allege that misstatements made to them regarding Shi and the status of a GSK China internal investigation “caused Plaintiffs to agree to conduct the initial investigation, and it was this investigation that led to their arrest, imprisonment, and resulting damages. (Compl. ¶¶ 151, 154, 156.) However, as explained above, there is no allegation that there were any attendees from either GSK PLC or GSK LLC at the April 15, 2013 meeting when the alleged misrepresentations were made. *Id.* at ¶ 50. As there are no such allegations, Plaintiffs’ fraud claims must be dismissed. *Davis*, 2015 WL 3555301 at \*1, 4-5 (dismissing claim for fraud against parent corporation because plaintiff “fails to show how [defendant] was involved in the alleged conduct in any way, other than being the parent company of the company that” is alleged to have caused the injury).

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<sup>10</sup> Further, a number of courts in this circuit have held that a corporation cannot engage in a RICO conspiracy with its own subsidiaries and employees. *See, e.g. Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, No. 07-2860(GEB), 2008 WL 5413105, at \*13 (D.N.J. Dec. 23, 2008) (parent and subsidiary incapable of conspiring, and “an alleged intro-corporate conspiracy comprised solely of a corporation acting in concert with its officers and employees should not be considered as involving separate actors conspiring under the law”); *Castle v. Crouse*, No. 03-5252, 2004 WL 257389, at \*6 (E.D. Pa. Feb.11, 2004) (“a corporate entity cannot conspire with its employees.”).

4. Plaintiffs' Claim For Conspiracy Fails Because Plaintiffs Allege No Malice By Either GSK Defendant

Plaintiffs' claim for civil conspiracy fails for two reasons. First, as with all other claims, there are no factual allegations that either GSK PLC or GSK LLC made any agreement among themselves. Second, Plaintiffs fail to allege any facts from which this Court could plausibly infer the essential element of malice.

To state a claim for conspiracy under Pennsylvania law, plaintiffs must show: (1) a combination of two or more persons acting with a common purpose to do an unlawful act or to do a lawful act, by unlawful means or for an unlawful purpose; (2) an overt act done in pursuance of the common purpose; and (3) actual legal damage. *Morilus v. Countrywide Home Loans, Inc.*, 651 F. Supp. 2d 292, 312 (E.D. Pa. 2008). Additionally, there must be a claim of malice or an intent to injure. *Morilus*, 651 F. Supp. 2d at 313. "Bald assertions that certain actions were malicious are insufficient; it must be alleged that the *sole* purpose of the conspiracy was to injure Plaintiffs." *Id.* (internal quotation and citation omitted) (emphasis in original).

Plaintiffs' claim for civil conspiracy fails because Plaintiffs allege no facts that could allow the court to infer that GSK PLC or GSK LLC harbored any intent to harm Plaintiffs in 2013. Moreover, even if the alleged actions of GSK China or GSK Singapore employees could be imputed to the GSK Defendants (which they cannot), Plaintiffs still fail to allege the essential element of malice against them. Rather, Plaintiffs allege that the GSK Defendants were motivated by their own self-interest: "[the GSK Defendants'] objective in retaining Plaintiffs was to create a dossier on the whistleblower . . . to frame her as a vindictive former employee with a grudge in order to cover-up their conspiracy and obstruct an ongoing investigation into it." (See Compl. ¶ 2.) "[The GSK] Defendants' *true motive* was to use Plaintiffs to discredit the whistleblower and cover up their illegal scheme." (*Id.* at ¶ 1.) (emphasis added). In fact,

Plaintiffs allege facts suggesting GSK China employee Reilly warned Plaintiffs about the fall-out of their report: that Reilly allegedly warned Humphrey that Shi had read the report and would be “coming after” him; and that Reilly informed Humphrey that Reilly planned to leave the country. (*Id.* at ¶¶ 8, 89.) Because the purported conspirators are alleged to have been “guided by personal interests separate from any alleged desire to cause harm to” the plaintiffs, the claim for civil conspiracy must be dismissed. *Morilus*, 651 F. Supp. 2d at 313.

5. Plaintiffs’ Claim For Intentional Infliction Of Emotional Distress Fails To Allege Severe Emotional Distress

First, as previously noted, Plaintiffs’ claims must fail as the GSK Defendants are not alleged to have been involved in any activity directed at or involving Plaintiffs. Second, even if the alleged GSK China employees’ action(s) could be imputed to GSK PLC or GSK LLC (which they cannot), Plaintiffs’ “threadbare legal conclusions” that they suffered “severe emotional distress” do not plausibly state a claim for relief. (Compl. ¶ 162.); *see Robinson v. Family Dollar, Inc.*, No. 14-03189, 2015 WL 3400836, at \*6 (E.D. Pa. May 27, 2015) (allegation that defendants “caused plaintiff to suffer severe emotional distress” are insufficient to state a plausible claim of intentional infliction of emotional distress). Moreover, claims for “both intentional and negligent infliction of emotional distress require a manifestation of physical impairment resulting from the distress.” *Adams v. U.S. Airways Grp., Inc.*, 978 F. Supp. 2d 485, 497 (E.D. Pa. 2013). Plaintiffs make no such allegation, and this claim therefore must be dismissed.

6. Plaintiffs’ Claim For Negligent Infliction Of Emotional Distress Fails Because Plaintiffs’ Cannot Allege Proximate Cause

Plaintiffs’ claim for negligent infliction of emotional distress also fails. First, neither GSK PLC nor GSK LLC is alleged to be involved in or knowledgeable about efforts to engage Plaintiffs to conduct an investigation of Shi. Moreover, it was the intentional actions of the

Chinese government in arresting, prosecuting, and imprisoning defendants that caused Plaintiffs harm, not the actions of any GSK employees, and the claim must therefore be dismissed for lack of proximate cause.

The U.S. District Court for the Middle District of Pennsylvania addressed a similar situation in *Deitrick v. Costa*, No. 4:06-CV-01556, 2015 WL 1606641, at \*9 (M.D. Pa. Apr. 9, 2015). In *Deitrick*, the complaint alleged plaintiffs' injuries resulted from a physical altercation at a police station during which police officers were "detaining and/or assaulting the [p]laintiff." *Id.* Although the *Deitrick* plaintiff sought to causally connect this incident to the defendant, the court dismissed this claim: "even if some as yet unknown act of negligence by defendant . . . is casually related to the police station incident, the intentional conduct of third persons is a superseding cause of the requisite physical impact. Accordingly, the negligent infliction of emotional distress claim should be dismissed." *Id.* at \*9. In this case, Plaintiffs allege they suffered harm at the hands of Chinese authorities while in prison. (*See* Compl. ¶¶ 91-107.) Any causal link to any GSK entity is therefore broken, and Plaintiffs' claim must be dismissed.

#### **E. The Complaint Must Be Dismissed For Failure To Join An Indispensable Party**

Plaintiffs seek to evade the arbitration clause in the Consultancy Agreement by strategically substituting the non-signatory GSK Defendants for the party actually involved in the allegations contained in Plaintiffs' complaint: GSK China. Every allegation in the Complaint revolves around services performed by ChinaWhys for GSK China. GSK China, which has been strategically left unnamed, is a necessary and indispensable party to this proceeding.

Federal Rule of Civil Procedure 12(b)(7) permits dismissal of an action for failure to join a party under Rule 19. Federal Rule of Civil Procedure 19 in turn determines whether a non-joined party is necessary, indispensable, and must be joined. The Court must, therefore, as a

preliminary matter determine whether joinder is compulsory under Rule 19(a). *Dickson v. Murphy*, 202 Fed. Appx. 578, 580 (3d Cir. Pa. 2006). If joinder is required but would divest the court of jurisdiction, the Court must then determine whether the non-joined party is indispensable under Rule 19(b). *Id.*

If the non-joined party is indispensable, the action must be dismissed.

1. GSK China Is A Necessary Party Under Rule 19(a), And Joinder Is Not Feasible

Under Rule 19(a), a non-joined party will be deemed necessary and joinder compulsory under two disjunctive circumstances. First, if “in that party’s absence, the Court cannot afford complete relief among existing parties” (Fed. R. Civ. P. 19(a)(1)(A)), or second, if disposition of the action would impair the non-joined party’s ability to protect its interest or “leave an existing party subject to a substantial risk of incurring double, multiple or otherwise inconsistent obligations because of the interest.” Fed. R. Civ. P. 19(a)(1)(B).

Here, all conduct upon which Plaintiffs predicate their causes of action was allegedly performed by GSK China, not the GSK Defendants. Plaintiffs cannot and do not cite to a single direct contact or encounter with the GSK Defendants. Instead, the Complaint is rife with allegations rooted in the Consultancy Agreement. (*See* Compl. at ¶ 50 (alleging that initial meeting with Plaintiffs took place at GSK China office with GSK China officials); ¶ 65 (alleging that follow-up meeting and collection of investigative material was again attended at and collected from GSK China); ¶ 70 (alleging that Plaintiffs’ Investigation Report was provided to GSK China officials); ¶¶ 71, 72, 113, 116 (alleging bribery and misconduct by GSK China); ¶¶ 79, 82, 83 (alleging that GSK China counsel requested further investigative work from Plaintiffs’); ¶ 84 (alleging that GSK China head of business development also requested investigative work from Plaintiffs).)

As such, neither Plaintiffs nor the GSK Defendants can be afforded complete relief absent GSK China's joinder, as any prospective liability would lie with GSK China, not the GSK Defendants. *See Carl Schroeter GmbH v. Crawford & Co.*, 2009 U.S. Dist. LEXIS 43488 (E.D. Pa. May 19, 2009) ("Plaintiffs' desire to hold [parent] Crawford liable for the acts and omissions of [subsidiary] Crawford Venezuela renders Crawford Venezuela a necessary party to this action"). As a Chinese company which is not alleged to have engaged in any activities in Pennsylvania, (*see* Ex. 9), GSK China is not subject to the personal jurisdiction of the court, and so, joinder is not feasible. Because joinder is not feasible, the Court must proceed to determine whether GSK China is an indispensable party under Rule 19(b), in which case dismissal is the appropriate remedy. *Carl Schroeter GmbH v. Crawford & Co.*, 2009 U.S. Dist. LEXIS 43488 at \*8 (E.D. Pa. May 19, 2009) (dismissal is appropriate where "joinder is not feasible because, for instance, the court lacks personal jurisdiction over the absent party.").

2. GSK China Is An Indispensable Party Under Rule 19(b), Requiring Dismissal Of This Action

The analysis under Rule 19(b) turns upon whether a Court, "in equity and good conscience," should allow the litigation to proceed without the non-joined parties. Fed. R. Civ. P. 19(b). Factors to be weighed in making this determination include: "[F]irst, to what extent a judgment rendered in the person's absence might be prejudicial to the person or those already parties; second, the extent to which, by protective provisions in the judgment, by the shaping of relief, or other measures, the prejudice can be lessened or avoided; third, whether a judgment rendered in the person's absence will be adequate; fourth, whether the plaintiff will have an adequate remedy if the action is dismissed for nonjoinder." Fed. R. Civ. P. 19(b)(1)-(4).

Applying these tests to the present case compels the conclusion that GSK China is indispensable. A judgment rendered in GSK China's absence would prejudice not only Plaintiffs

and the GSK Defendants, as discussed *supra*, but GSK China itself, as such a judgment would be, in effect, entirely “hollow” as to it. *Jurimex Kommerz Transit G.m.b.H. v. Case Corp.*, 201 F.R.D. 337, 340-341 (D. Del. 2001), *aff’d* 2003 U.S. App. LEXIS 7690 (3d Cir. Apr. 23, 2003) (“A judgment in defendant's favor would not be ‘adequate’ because Plaintiffs could subsequently sue the [absent] Subsidiaries in a different forum based on essentially the same facts, while a judgment in Plaintiffs' favor may be ‘hollow’ because the proper defendant was never joined”).

In *Jurimex*, the plaintiff, an Austrian corporation, sought to avail itself of U.S. courts by asserting contract and tort claims against a U.S. parent for conduct allegedly committed by the parent’s foreign subsidiaries. Finding that “most of [p]laintiffs’ interactions and negotiations regarding the Transaction were with the Subsidiaries and not with [d]efendant,” the court deemed the absent subsidiaries indispensable. *Id.* at 340.

This Court reached the same conclusion in *Carl Schroeter GmbH v. Crawford & Co.* when presented with similarly misplaced claims strategically asserted, like those brought by Plaintiffs here, against a domestic parent in lieu of its foreign subsidiary. No. 09-946, 2009 U.S. Dist. LEXIS 43488, 11-12 (E.D. Pa. May 19, 2009) (noting that “when a defendant is sued solely in connection with its subsidiary's conduct, the subsidiary is a necessary and indispensable party” and accordingly dismissing complaint where “foreign plaintiffs [sued] American corporate defendant, seeking to hold that defendant liable for its [absent] foreign subsidiary’s conduct.”).

Significantly, Plaintiffs have an adequate remedy and forum should the Court dismiss this litigation for non-joinder and, more specifically, one to which they have agreed. The Consultancy Agreement provides for the arbitration of “all disputes arising out of or in connection” with the Agreement. (*See* Ex. 1, Consultancy Agreement § 11.) Arbitration would

allow all relevant parties to rightfully adjudicate their respective claims, and dismissal is thus warranted here.

Thus, this Court should dismiss this action for non-joinder of GSK China, a necessary and indispensable party.

**F. Causes Of Action III (Fraud), IV (Intentional Infliction Of Emotional Distress) And V (Negligent Inflict of Emotional Distress) Are Barred By Pennsylvania's Statute Of Limitations.**

In the Commonwealth of Pennsylvania, “[t]he limitations period for any claim begins to run ‘from the time the cause of action accrue[s].’” *Beasley v. Young, Ricchiti, Caldwell & Heller, LLC*, No. 2873 EDA 2012, 2013 WL 11250696, at \*5 (Pa. Sup. Ct. Nov. 4, 2013) (*citing* 42 Pa. C.S.A. §§ 5502(a)). Specifically, “a cause of action accrues when the plaintiff could have first maintained the action to a successful conclusion. . . . [T]he statute of limitations begins to run as soon as the right to institute and maintain a suit arises. . . . Once a cause of action has accrued and the prescribed statutory period has run, an injured party is barred from bringing his cause of action.” *Fine v. Checcio*, 870 A.2d 850, 857 (Pa. 2005).

Pursuant to 42 Pa. C.S.A. §§ 5524(7), claims concerning fraud, intentional infliction of emotional distress and negligent infliction of emotional distress are governed by a two-year statute of limitations. The Complaint alleges that the GSK Defendants made false representations and intentionally misled Plaintiffs between April and July 2013 (*See* Compl. ¶¶ 49, 56, 64-65, 67, 70, 79-81, 84, 86, 91, 150-170.) Therefore, because the Complaint was served on the GSK Defendants in November 2016, which was more than three years from the latest date at which the alleged causes of action began to accrue, counts III, IV and V are time-barred. As the statutory framework in Pennsylvania clearly addresses, Plaintiffs are not entitled to toll their claims merely because of Humphrey’s and Yu’s incarceration. *See* 42 Pa. C.S.A. § 5533(a) (providing that “imprisonment does not extend the time limited by this subchapter for the

commencement of a matter.”); *see also Johnson v. Romig*, No. 11-02052, 2013 WL 6916428, at \*2 (Pa. Dec. 19, 2013). Accordingly, Counts III, IV and V in the Complaint should be dismissed with prejudice.

### **G. Plaintiffs Lack Standing To Assert Their Purported RICO Claims**

Section 1964(c) identifies four factors that must be satisfied to establish standing for a civil RICO claim: (1) the plaintiff must be a “person” (2) who sustains injury (3) to its “business or property” (4) “by reason of” the defendant’s violation of § 1962. Thus, a RICO “plaintiff only has standing if, and can only recover to the extent that, he has been injured in his business or property by the conduct constituting the violation.” *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985). Critically, RICO does not encompass foreign injuries to business or property. In a very recent opinion, *RJR Nabisco v. European Community, et al*, 136 S. Ct. 2090 (2016), the Court held that “a private RICO plaintiff... must allege and prove a *domestic* injury to its business or property.” *Id.* at 2106 (emphasis in original). Thus, RICO “does not allow recovery for foreign injuries.” *Id.* at 2111. As these are the only injuries alleged by Plaintiffs, their RICO claims must be dismissed.

The only injuries to business or property claimed by Plaintiffs in connection with their RICO claims are that “Plaintiffs’ business was destroyed and their prospective business ventures eviscerated” (Compl. ¶132) and that they have allegedly been “put out of business.” (Compl. ¶145.)<sup>11</sup> Plaintiffs allege that their business, ChinaWhys, had numerous clients in the U.S., but they fail to mention that it only had offices in China. (*See* Exs. 10-13.)<sup>12</sup> Although

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<sup>11</sup> Plaintiffs’ allegations of personal injuries suffered while imprisoned are not cognizable under RICO. *See, e.g., Magnum v. Archdiocese of Philadelphia*, 253 F. App’x 224, 227 (3d Cir. 2007) (“[P]hysical or emotional harm to a person is not property under civil RICO. Similarly, losses which flow from personal injuries are not property under RICO.”); *Genty v. Resolution Trust Corp.*, 937 F.2d 899, 918–19 (3d Cir. 1991) (“RICO plaintiffs may recover damages for harm to business and property only, not physical and emotional injuries[.]”).

<sup>12</sup> *See* discussion *supra* at Section III(C).

Plaintiffs attempt to manufacture a U.S. connection by alleging that Humphrey had communications with employees of GSK China while he was travelling in the U.S., they make no claim that Humphrey’s travel had anything to do with the GSK engagement—because it did not—and the communications themselves exclusively concerned ChinaWhys’ activities in China. (Compl. ¶ 83 (alleged call between Humphrey and GSK China (R&D) counsel concerning Chinese Public Security Bureau research); Compl. ¶ 84 (alleged request from GSK China head of business development concerning research into various Chinese government entities)). In short, Plaintiffs make no allegation that ChinaWhys performed any work outside of China relating to its engagement by GSK China, and none of the communications through which Plaintiffs maintain they were deceived were made by employees of GSK LLC, the only U.S. entity involved on either side of this litigation.

Given these facts, any injury suffered by ChinaWhys is indisputably foreign. Although the Court in *RJR Nabisco* did not address the definition of a “foreign injury,” it explained the question before it as “whether the court has authority to recognize a cause of action for injury *suffered overseas*” (*id.* at 2109) (emphasis added), and concluded that “damages claims [which] rest entirely on *injury suffered abroad* ... must be dismissed.” (*id.* at 2111) (emphasis added). Here, ChinaWhys is a Chinese company that is alleged to have been damaged when its principals, who lived and worked in China, were imprisoned in China after they performed work in China at the request of GSK China, another China company. Plaintiffs claim that ChinaWhys had U.S. clients is irrelevant—those clients had no involvement whatsoever in the events alleged in the Complaint, nor are their locations relevant to determining where ChinaWhys was injured—only ChinaWhys’ location is relevant to answering this question.

The handful of cases to consider the definition of a “foreign injury” since *RJR Nabisco* support this conclusion. In *Bascunan v. Els*, 2016 WL 5475998 (S.D.N.Y. Sept 28, 2016), the Court concluded that losses suffered by a Chilean plaintiff were foreign losses, despite the fact that a number of the underlying allegations, such as physical misappropriation of bearer shares from a bank safety deposit box, had occurred in New York. The *Bascunan* court also concluded that injuries suffered by a corporate plaintiff are not “domestic” when the plaintiff is incorporated in a foreign country and does not have a U.S. principal place of business. *Id.* at \*6 (“[If] the Corporate Plaintiffs suffered economic injury, they too, suffered their injuries abroad because each was incorporated in the British Virgin Islands or Chile, and the Amended Complaint has not alleged that their principal place of business is in the U.S.”)) Notably, either approach to determining the location of injury that was considered by the *Bascunan* court—(i) location of the injury or (ii) location of the conduct leading to the injury—would lead in the present case to the conclusion that any injury suffered by ChinaWhys is foreign, for ChinaWhys was located in China and only alleges injury arising from conduct occurring in China.

In *Union Commercial Services Ltd v. FCA International*, 2016 WL 6650399 (E.D. Mich. Nov. 10, 2016), the court applied a “substantial effects” test, derived from antitrust law, to determine whether an injury was domestic under *RJR Nabisco*. Although the plaintiff alleged that it had a business office and bank accounts in Florida, and that funds relating to the alleged RICO violations had been transferred through them, the court concluded that “defendants’ alleged conduct was directed at, and any effects were felt by, plaintiff’s business or property interests outside of the U.S.” *Id.* at \*5. Thus, despite plaintiffs’ allegations of U.S. connections—allegations with an actual connection to the underlying claims, unlike the ChinaWhys allegations here—the court dismissed the complaint for failure to allege a domestic

injury, based upon the foreign nexus of the underlying injury. Similarly, in *Exeed Industries v. Younis*, 2016 WL 6599949 (N.D. Ill. Nov. 8, 2016), the court dismissed RICO claims alleging that U.S. suppliers of a United Arab Emirates company were duped into paying fraudulent invoices whose proceeds were used by the defendants to finance U.S. land purchases. The court concluded that “the few cases to address the issue of domestic injury post-*RJR Nabisco* have interpreted it to mean that an injury arises where it was initially suffered by the plaintiff,” (*id.* at \*3) and that “the fact that a large number of Plaintiff’s suppliers have offices in the U.S. does not speak to where the injury was felt by the Plaintiffs themselves—that question can only be answered by looking to the Plaintiffs’ business operations in the UAE.” *Id.*

Here, ChinaWhys is a Chinese company, and its only allegations of conduct allegedly directed against it involve actions by GSK China in China. Any injuries that ChinaWhys has suffered are foreign, and Plaintiffs’ RICO claims must therefore be dismissed.

## **V. CONCLUSION**

For the reasons set forth above, the GSK Defendants respectfully request that the Court compel arbitration pursuant to the Consultancy Agreement, and stay all proceedings pending conclusion of such arbitration. In the alternative, for the reasons set forth herein, the GSK Defendants request that the Court dismiss the entirety of Plaintiffs complaint.

Dated: January 16, 2017

Respectfully submitted,

/s/ Jayne A. Risk

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GlaxoSmithKline plc.*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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PETER HUMPHREY, YU YINGZENG, and  
CHINAWHYS COMPANY LTD,

Plaintiffs,

v.

GLAXOSMITHKLINE PLC and  
GLAXOSMITHKLINE LLC,

Defendants.

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Civil Action No.: 2:16-CV-5924

**ORDER**

AND NOW, this \_\_\_\_ day of \_\_\_\_\_, 2017, upon consideration of Defendants GlaxoSmithKline PLC and GlaxoSmithKline LLC's Motion to Compel Arbitration or, in the Alternative, Motion to Dismiss the Complaint, it is hereby ORDERED that the motion is GRANTED. The above-referenced matter is referred to arbitration before the China International Economic and Trade Arbitration Commission. All further proceedings in this matter are STAYED pending disposition of arbitration.

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HON. NITZA I. QUIÑONES-ALEJANDRO  
United States District Judge

**CERTIFICATE OF SERVICE**

I certify that on January 16, 2017 , I caused a copy of the foregoing Motion to Compel Arbitration or, in the Alternative, Motion to Dismiss the Complaint, along with the accompanying Memorandum of Law and exhibits thereto, to be served on the following individuals via the means specified below:

**Via the Court's CM/ECF System:**

Joan D. Gallagher  
**GALLAGHER & TURCHI**  
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575 Lexington Avenue  
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New York, NY 10022

By: /s/ Jayne A. Risk  
Jayne A. Risk

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

PETER HUMPHREY, YU YINGZENG, and  
CHINAWHYS COMPANY LTD,

Plaintiffs,

v.

GLAXOSMITHKLINE PLC and  
GLAXOSMITHKLINE LLC,

Defendants.

Civil Action No.: 2:16-CV-5924

**DECLARATION OF JAYNE ANDERSON RISK IN  
SUPPORT OF DEFENDANTS' MOTION TO COMPEL  
ARBITRATION, OR, IN THE ALTERNATIVE,  
MOTION TO DISMISS THE COMPLAINT**

JAYNE ANDERSON RISK, an attorney duly admitted to practice law in the U.S. District Court for the Eastern District of Pennsylvania, affirms, under penalty of perjury, the following to be true:

1. I am a member in good standing of this Court, and a partner in the law firm of DLA Piper LLP (US), counsel to GlaxoSmithKline plc ("**GSK PLC**") and GlaxoSmithKline LLC ("**GlaxoSmithKline LLC**") (together, the "**GSK Defendants**") in the above-captioned matter. I submit this Declaration in support of Defendants' Motion To Compel Arbitration, Or, In The Alternative, Motion To Dismiss The Complaint.

2. Attached hereto as Exhibit 1 is a true and correct copy of a consultancy agreement dated April 25, 2013 including Appendix A ("**Consultancy Agreement**") entered into by GlaxoSmithKline (China) Investment Co. Ltd. ("**GSK China**") and ChinaWhys (Shanghai) Consulting Co. Ltd. ("**ChinaWhys (Shanghai)**").

4. Attached hereto as Exhibit 2 is a true and correct screenshot taken on January 14, 2017 of an August 27, 2013 article published by *China Daily USA* which is publicly available at [http://usa.chinadaily.com.cn/china/2013-08/27/content\\_16922439.htm](http://usa.chinadaily.com.cn/china/2013-08/27/content_16922439.htm).

5. Attached hereto as Exhibit 3 is a true and correct screenshot taken on December 7, 2016 of an article in *The Fraud Examiner* dated May 2013 entitled “How Fraud Investigation Just Got Harder in China” which is publicly available at <http://www.acfe.com/fraud-examiner.aspx?id=4294978054>.

6. Attached hereto as Exhibit 4 is a true and correct screenshot taken on January 14, 2017 of the U.S. Department of Justice’s July 2, 2012 press release which is publicly available at <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report>.

7. Attached hereto as Exhibit 5 is a true and correct screenshot taken of the Department of Justice website on January 14, 2017 of the Corporate Integrity Agreement dated July 2, 2012 which is publicly available at <https://www.justice.gov/sites/default/files/opa/legacy/2012/07/02/hhs-oig-corp-integrity-agreement.pdf>.

8. Attached hereto as Exhibit 6 is a true and correct screenshot taken on January 14, 2017 of a GSK press release dated September 19, 2014 titled “GSK China Investigation Outcome” which is publicly available at <http://www.gsk.com/en-gb/media/press-releases/2014/gsk-china-investigation-outcome/>.

9. Attached hereto as Exhibit 7 is a true and correct screenshot taken on January 14, 2017 of a U.S. Securities and Exchange Commission (“U.S. S.E.C.”) press release which is publicly available at <https://www.sec.gov/litigation/admin/2016/34-79005-s.pdf>.

10. Attached hereto as Exhibit 8 is a true and correct copy of a U.S. SEC administrative proceeding order dated September 30, 2016 *In the Matter of GlaxoSmithKline pc* (File No. 3-17606) which is publicly available at <https://www.sec.gov/litigation/admin/2016/34-79005.pdf>.

11. Attached hereto as Exhibit 9 is a Declaration of GSK China.

12. Attached hereto as Exhibit 10 is a true and correct screenshot taken on January 14, 2017 of a page from ChinaWhys' website entitled "An International Business Risk Advisory Firm with Eyes in China" which is publicly available at <http://chinawhys.com/aboutus.htm>.

13. Attached hereto as Exhibit 11 is a true and correct screenshot taken on December 7, 2016 of Peter Humphrey's biography on ChinaWhys' website which is publicly available at <http://chinawhys.com/peter.htm>.

14. Attached hereto as Exhibit 12 is a true and correct screenshot taken on December 7, 2016 of Yingzeng Yu's biography on ChinaWhys' website which is publicly available at <http://chinawhys.com/yingzeng.htm>.

17. Attached hereto as Exhibit 13 is the Declaration of GSK PLC

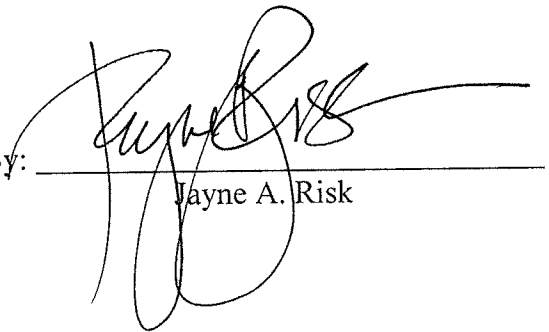
18. Attached hereto as Exhibit 14 is the Declaration of GSK LLC

19. Attached hereto as Exhibit 15 is a true and correct screenshot taken on January 14, 2017 of an article on Lexology titled "*Conviction of Private Investigators in China Further Complicates Anti-Corruption Compliance Efforts*" which is publicly available at [www.lexology.com/library/detail.aspx?g=dbb77b00-ce7f-4606-8b65-f0148297d6b6](http://www.lexology.com/library/detail.aspx?g=dbb77b00-ce7f-4606-8b65-f0148297d6b6).

20. Attached hereto as Exhibit 16 is a true and correct screenshot taken on January 14, 2017 of an article published by CCTV.com (English) on August 27, 2013 titled "Foreign

Couple Arrested for Selling Personal Information” which is publicly available at <http://english.cntv.cn/program/newshour/20130827/102867.shtml>.

Dated: Philadelphia, Pennsylvania  
January 16, 2017

By:   
Jayne A. Risk

To: ChinaWhys (Shanghai) Consulting Co Ltd (in Chinese 摄连咨询(上海)有限公司)

Address: 35-107 CITIC Square, 1168 Nanjing West Road, Shanghai 200041, China

Date: April 25, 2013

Dear Mr. Peter Humphrey,

**CONSULTANCY AGREEMENT (this “Agreement”)**

We set out below the terms on which you have agreed to provide certain consultancy services to us with respect to the proposed investigation and inquiry activities to be detailed in the proposal for Project Scorpion (“the Project”).

**1. SERVICES**

- 1.1 We hereby engage you to provide the following services (“the Consultancy Services”) to us and you agree to provide the Consultancy Services to us using due care and skill. The scope of Consultancy Services is detailed in the Project Proposal as attached in Appendix A hereto.
- 1.2 You will provide the Consultancy Services to us at such times and at such locations as we shall agree from time to time. You shall ensure that when carrying out the Services at a GSK site, you conform with all GSK’s policies and procedures with regard to working conditions, safety, security and similar matters and agree at all times during the performance of the Services to comply with such reasonable requirements as may be notified to you from time to time.
- 1.3 You will only contact third parties in pursuance of the Consultancy Services after our express written consent that you may do so to enable us to put in place a Confidentiality Agreement with that third party if we require it. Where approval has been given to contact any third party, you will agree in advance with us what information you may disclose about the Project and our business to that third party. We may specify that you are not permitted to disclose that you are working for GlaxoSmithKline when you make any authorised contact with third parties and you agree to respect any such requirement absolutely.
- 1.4 You will at our request produce and submit to us a final presentation and written report of all recommendations and findings arising out of the Consultancy Services immediately prior to the termination of this Agreement.

- 1.5 You represent that you are under no obligation which is inconsistent with this Agreement and that you will not enter into any agreement with a third party, the terms of which may be inconsistent with this Agreement.
- 1.6 You shall carry out the Consulting Services always in a lawful and ethical manner. The term 'ethical' used in this policy means: in compliance with all laws, regulations, legal and professional guidelines, and in a manner not likely to result in harm to GSK's reputation or image.

**2. COMMENCEMENT DATE**

This Agreement will commence on the signature by the authorized representative of each party and will continue, subject to the provisions of Clause 8, until the Consulting Services is completed.

**3. FEES AND EXPENSES**

- 3.1 For Services actually rendered hereunder, we agree to pay you a fixed sum of **[RMB 220,000]** (exclusive any applicable business Tax or VAT) ("Service Fees"). Fifty per cent (50%) of the Service Fees will be payable within thirty (30) days of the date of your invoice, which you will submit to us during the last week of each calendar month. The payment term for subsequent invoice is 60 days. You will provide a detailed summary of the Consultancy Services provided and of the hours worked for the work period invoiced.
- 3.2 We will pay your reasonable round-trip travelling and living expenses from your home to the consulting site while travelling at our request subject to the provision of proper receipts. Claims for travelling and living expenses shall be submitted by you at the end of each trip taken during which this Agreement remains in effect, and we will pay such expenses after receipt and approval thereof. Where any travel will require you to travel to another country than your normal country of residence, express written consent from us will be required before incurring such expenditure. These out-of-pockets shall not exceed the equivalent of 15% of Service Fees.
- 3.3 The payments referred to in Clauses 3.1 and 3.2 are full and complete compensation for all obligations assumed under this Agreement and for all inventions, improvements, patent rights or other Intellectual Property Rights (as defined in Clause 5 below) assigned under this Agreement.

- 3.4 You will be responsible for all costs in respect of the fees paid under this Agreement including, without limitation, the payment for and provision of all benefits and national insurance contributions and the payment of all employment and income related taxes. You agree to indemnify us in respect of any claims by the relevant authorities against us in respect of employment or income tax or national insurance or any other costs relating to the provision of the Services hereunder.

**4. CONFIDENTIALITY**

- 4.1. You agree to treat as secret and confidential and will not at any time nor for any reason disclose or permit to be disclosed to any person (except in accordance with Clause 1.3 above) or otherwise make use of or permit to be made use of, any information relating to the Products(s) / Project(s) whether disclosed by us or generated by you or to any technology, technical processes, business affairs, patents or finances or any such information relating to us or to any Affiliate, supplier, customer or client of ours ("Information") where knowledge or details of the Information was received, acquired or developed by you during the period of this Agreement.
- 4.2 Upon termination of your appointment under this Agreement for whatever reason, you shall forthwith deliver up to us all Information which may be in your possession, custody or control and which are our or our Affiliates' property or which otherwise relate in any way to the business or affairs of us or our Affiliates and no copies of the same or any part thereof will be retained by you. Such return will not affect your obligations under Clause 4.1.
- 4.3 The above obligations of confidentiality and non-use shall not apply to information and data which you can show were already known to you, information and data which are or become part of the public domain through no fault of your own and information and data which are given to you by a third party who has a right to do so.
- 4.4 The provisions of this Clause 4 will survive termination of this Agreement.
- 4.5 Further, the Confidentiality Agreement already signed between us shall be deemed to form part of this Agreement.

**5. INTELLECTUAL PROPERTY RIGHTS**

- 5.1 You shall disclose promptly to us any inventions, improvements, derivative works or alternatives made or conceived by you, either alone or jointly with others, in the course of or as a result of the work done hereunder, or as a consequence of confidential information supplied for the purposes hereof, directly or indirectly, by us or our affiliates or agents (which, for the avoidance of doubt, shall include their directors, officers or employees). You hereby assign to us or to any Affiliates of ours, to the extent permitted by law, all Intellectual Property Rights in any work generated by you on or after the commencement of this Agreement and pursuant to this Agreement and you agree to provide all necessary assistance as we may consider necessary in order to assign such Intellectual Property Rights to us or any Affiliate of ours, including, but not limited to, the execution of such documents as may be required to file applications for and obtain Intellectual Property Rights in any country in our or our Affiliates' name.
- 5.2 The term "Intellectual Property Rights" means all patents, trademarks, service marks, designs (whether or not registered) and applications therefor, present and future copyright, database rights, trade secrets, domain names, rights in know-how and other rights of confidence and all other rights of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world.
- 5.3 You hereby grant (and shall procure the grant of) to us or to any of our Affiliates at our option a non-exclusive, royalty-free, world-wide, perpetual, irrevocable, assignable licence (with the right to licence freely) of all Intellectual Property Rights created prior to the commencement of this Agreement which are necessary for the receipt and use of each deliverable arising out of the Consultancy Services.

**6. NOTICES**

- 6.1 Any notices, payments or statements to be made under this Agreement shall be made to you at the address to which this Agreement is directed and to Mr. Peter Humphrey at the ChinaWhys address stated above, or at such other address later designated in writing by the other party for such purposes.

- 6.2 Any notice required by this Agreement to be given by either of us to the other will be in writing and will be served by sending it by registered mail, recorded delivery courier or delivered by hand and any receipt issued by the postal authorities or by the courier or on hand delivery will be inclusive evidence of the fact and the date of posting of any such notice.

**7. INDEPENDENT CONTRACTOR RELATIONSHIP**

You agree that you will be serving under this Agreement as an independent contractor and that the relationship of employer and employee shall not exist between you and ourselves at any time as a result of the arrangements contemplated by this Agreement.

**8. TERMINATION AND SURVIVAL TERMS**

- 8.1 We may by giving notice in writing to you terminate this Agreement in the event that you:

8.1.1 act in breach of any of the terms of this Agreement which in the case of a breach capable of remedy, has not been remedied by you within ten (10) days of receipt by you of a notice from us specifying the breach and requiring its remedy;

8.1.2 are judged in our sole discretion, to be incompetent or negligent in the provision of the Consultancy Services.

- 8.2 The Agreement may be cancelled at any time by us for any reason whatsoever, by giving You notice in writing.

- 8.3 Upon termination, You will be compensated for the Consulting Services actually performed and reimbursed for expenses actually and reasonably or non-cancellable in accordance with the terms hereof.

- 8.4 Clauses 4, 5, 6, 9, 10, 11 and 12 of this Agreement shall survive the expiration or termination of this Agreement.

**9. DATA PROTECTION**

You consent to us holding and processing, both manually and electronically, any data it collects regarding you for the purpose of administering and managing its business and for compliance with applicable procedures, laws and regulations.

**10. SYSTEMS**

You shall ensure that any deliverables provided to us under this Agreement shall:

- 10.1 be provided in a mutually agreed electronic format;
- 10.2 be free from defects, disabling codes, computer viruses, worms, logic bombs, Trojan horses and other information technology contaminants or unauthorised computer code and have been tested to be so; and
- 10.3 comply and function substantially in accordance with their related user documentation.

**11. GOVERNING LAW AND DISPUTE RESOLUTION**

This Agreement shall be governed in all respects by the laws of the People's Republic of China. All disputes arising out of or in connection with this Agreement shall be settled through friendly consultation between both parties. In case no settlement can be reached, either Party may submit the dispute to the China International Economic and Trade Arbitration Commission ("CIETAC") in Beijing for arbitration in accordance with the CIETAC rules of arbitration then in effect. The arbitration award shall be final and binding on the Parties.

**12. SEVERANCE**

Each clause of this Agreement is a distinct and severable clause and if any clause is deemed illegal, void or unenforceable, the validity, legality, or enforceability of any other clause or portion of this Agreement shall not be affected thereby.

**13. CONFLICT OF INTEREST**

While providing Services under this Agreement you agree that you shall not be engaged in or concerned with either directly or indirectly any other business or profession which either competes with ours or might otherwise cause a conflict of interest without our prior written consent. If in any doubt as to whether a conflict of interest might exist you should immediately discuss the matter with [Mr. Mark Reilly] before accepting such position.

**14. WAIVER**

The failure of a party in any instance to insist on the strict performance of the terms of this Agreement shall not be construed to be a waiver or relinquishment of any of the terms of this Agreement either at the time of the party's failure to insist upon strict performance or at any subsequent time.

**15. ENTIRE AGREEMENT**

15.1 This Agreement constitutes the whole and only agreement between the parties relating to the Services and any previous agreement will be deemed to have terminated. Each party acknowledges that in entering into this Agreement it is not relying upon any pre-contractual statement which is not attached to this Agreement. Except in the case of fraud, no party shall have any right of action against any other party to this Agreement arising out of or in connection with any pre-contractual statement except to the extent that it is repeated in this Agreement.

15.2 For the purposes of this clause, "**pre-contractual statement**" means any draft, agreement, undertaking, representation, warranty, promise, assurance or arrangement of any nature whatsoever, whether or not in writing, relating to the subject matter of this Agreement made or given by any person at any time prior to the date of this Agreement.

**16. FORCE MAJEURE**

16.1 Neither party shall be liable for any delay or failure in performing any of its obligations under this Agreement if the delay or failure results from events or circumstances beyond its reasonable control (including without limitation any acts or restraints of governments or public authorities, war, revolution, riot or civil commotion, acts of God or fire but excluding strikes and lockouts) ("Force Majeure") provided that the party so affected shall send to the other party a written notice within three (3) days of becoming aware of such Force Majeure giving full particulars thereof including the date of first occurrence, the circumstances giving rise to it and an indication of the duration of such circumstances.

16.2 If the period of delay or failure extends for sixty (60) days or more from the date of notification of the Force Majeure event to the other party, either party shall have the right to terminate the Agreement forthwith by written notice.

**17. LIABILITY**

17.1 You shall not be liable for any loss, damage or delay suffered by us insofar as such loss, damage or delay is directly attributable to instruction given or actions undertaken by us or on our behalf.

17.2 You shall indemnify us, our Affiliates and any servant or agent of ours against:

17.2.1 any loss or damage caused to any property of ours, our Affiliates or our servants or agents or any physical injury (including injury resulting in death) sustained by any servant or agent of ours by reason of any negligent or wilful act or omission of you at any time during the performance of the Consultancy Services; or

17.2.2 any claim demand or liability made against or incurred by us, our Affiliates or our servants or agents in respect of:

(i) any loss of or damage to any property of yours or injury (including injury resulting in death) sustained by you in the provision of the Consultancy Services unless such loss, damage or injury is caused by the negligent act or omission of us, our Affiliates or any of our servants or agents;

(ii) any loss, damage or injury (including injury resulting in death) sustained by any third party in the provision of the Consultancy Services in consequence of any negligence or wilful act or omission of you; or

(iii) the receipt or use of any Intellectual Property Rights assigned or licensed to us or any of our Affiliates under Clause 5 which infringes the Intellectual Property Rights of a third party.

If the foregoing terms and conditions are acceptable to you, we would be grateful if you could sign and return the enclosed duplicate copy of this Agreement.

**18. ANTI-BRIBERY AND CORRUPTION**

- 18.1 You acknowledge that you have received and read the 'Prevention of Corruption – Third Party Guidelines' (either in hard copy in Appendix or at <http://www.gsk.com/policies/Prevention-of-Corruption-Third-Party-Guidelines.pdf>) and agree to perform your obligations under the Agreement in accordance with the principles set out therein.
- 18.2 You shall comply fully at all time with all applicable laws and regulations, including but not limited to applicable anti-corruption laws, of the territory in which you conduct business with GSK.
- 18.3 You agree that you have not, and covenant that you will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorise, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting you or GSK in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery.
- 18.4 You shall not contact, or otherwise meet knowingly meet with any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of GSK and, when requested by GSK, only in the presence of a GSK designated representative.
- 18.5 For the purpose of this Agreement "Government Official" means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organisation such as the World Bank or United Nations; (e) any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office; who, when such Government Official is acting in an official capacity, or in an official decision making role, has responsibility for performing regulatory inspections, government authorisations or licenses, or otherwise has the capacity to take decisions with the potential to affect GSK business.
- 18.6 You represent that except as disclosed to GSK in writing prior to the commencement of this Agreement, you have not been convicted of or pleaded guilty to a criminal offence, including one involving fraud or corruption, that you are not now, to the best of your knowledge, the subject of any government investigation for such offenses, and that you are not now listed by any government agency as debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs.

- 18.7 You represent and warrant that except as disclosed to GSK in writing prior to the commencement of this Agreement: (1) you do not have any interest which directly or indirectly conflicts with your proper and ethical performance of this Agreement; and (2) you shall maintain arm's length relations with all third parties with which you deal for or on behalf of GSK in performance of this Agreement.
- 18.8 GSK shall have the right during the terms of this Agreement to conduct an investigation and audit of your activities under this Agreement to monitor compliance with the terms of this Agreement. You shall cooperate fully with such investigation or audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of GSK.
- 18.9 You shall ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on your books and records and each document upon which entries such books and records are based is complete and accurate in all material respects. You must maintain a system of internal accounting controls reasonably designed to ensure that you maintain no off-the-books accounts.
- 18.10 You agree that in the event that GSK believes that there has been a possible violation of the terms of this Agreement, GSK may make full disclosure of such belief and related information at any time and for any reason to any competent government bodies and its agencies, and to whomsoever GSK determines in good faith has a legitimate need to know.
- 18.11 GSK shall be entitled to terminate this Agreement with immediately on written notice to you, if you fail to perform your obligations in accordance with this Clause 18. You shall have no claim against GSK for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Clause 18. To the extent (and only to the extent) that the laws of the territory provide for any such compensation to be paid to you upon the termination of this Agreement, you hereby expressly agree (to the extent possible under the laws of the territory) to waive or to repay to GSK any such compensation or indemnity.

**19. Adverse Event Reporting**

- 19.1 GSK is required by law to report adverse events associated with GSK products to the relevant authorities. If in the course of providing the Services you receives a report of an adverse event related to a GSK product, you will attempt to obtain the reporter's name and contact details and the name and formulation of the product involved. You will either report the information to a member of GSK staff or to GSK using the contact details set out below within 24 hours. You will inform the reporter that a representative from GSK may contact them to request additional information. If the reporter is a patient or consumer, you will suggest that they should consult their doctor.

For reports of adverse events associated with medicinal products:

Tel: 400-183-3383 or 800-820-3383

- 19.2 If GSK identifies any reports of adverse events associated with GSK products in materials provided by you for the Consultancy Services, GSK will report such adverse events to the relevant authorities in accordance with its standard procedures. In this case, you agree to co-operate with, and provide further information to, GSK safety staff, within 24 hours, as requested.

Yours faithfully

For and on behalf of

[GLAXOSMITHKLINE (CHINA) INVESTMENT CO., LIMITED]

I agree to the above terms

For ChinaWhys (Shanghai) Consulting Co Ltd

摄连咨询(上海)有限公司

Signed:



Date: 26 April 2013

Name: Mr. Peter Humphrey

### **Prevention of Corruption – Third Party Guidelines**

The GSK Anti-Bribery and Corruption Policy (POL-GSK-007) requires compliance with the highest ethical standards and all anti-corruption laws applicable in the countries in which GSK (whether through a third party or otherwise) conducts business. POL-GSK-007 requires all GSK employees and any third party acting for or on behalf of GSK to ensure that all dealings with third parties, both in the private and government sectors, are carried out in compliance with all relevant laws and regulations and with the standards of integrity required for all GSK business. GSK values integrity and transparency and has zero tolerance for corrupt activities of any kind, whether committed by GSK employees, officers, or third-parties acting for or on behalf of the GSK.

**Corrupt Payments** – GSK employees and any third party acting for or on behalf of GSK, shall not, directly or indirectly, promise, authorise, ratify or offer to make or make any “payments” of “anything of value” (as defined in the glossary section) to any individual (or at the request of any individual) including a “government official” (as defined in the glossary section) for the improper purpose of influencing or inducing or as a reward for any act, omission or decision to secure an improper advantage or to improperly assist the company in obtaining or retaining business.

**Government Officials** – Although GSK’s policy prohibits payments by GSK or third parties acting for or on its behalf to any individual, private or public, as a “quid pro quo” for business, due to the existence of specific anticorruption laws in the countries where we operate, this policy is particularly applicable to “payments” of “anything of value” (as defined in the glossary section), or at the request of, “government officials” (as defined in the glossary section).

**Facilitating Payments** – For the avoidance of doubt, facilitating payments (otherwise known as “greasing payments” and defined as payments to an individual to secure or expedite the performance of a routine government action by government officials) are no exception to the general rule and therefore prohibited.

### **GLOSSARY**

The terms defined herein should be construed broadly to give effect to the letter and spirit of the ABAC Policy. GSK is committed to the highest ethical standards of business

dealings and any acts that create the appearance of promising, offering, giving or authorising payments prohibited by this policy will not be tolerated.

Anything of Value: this term includes cash or cash equivalents, gifts, services, employment offers, loans, travel expenses, entertainment, political contributions, charitable donations, subsidies, per diem payments, sponsorships, honoraria or provision of any other asset, even if nominal in value.

Payments: this term refers to and includes any direct or indirect offers to pay, promises to pay, authorisations of or payments of anything of value.

Government Official shall mean:

- Any officer or employee of a government or any department, agency or instrument of a government;
- Any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government;
- Any officer or employee of a company or business owned in whole or part by a government;
- Any officer or employee of a public international organisation such as the World Bank or United Nations;
- Any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or
- Any candidate for political office



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**CLIENT CONFIDENTIAL**

**21 April 2013**

To: Dr. Mark Reilly, Chairman  
GlaxoSmithKline (China) Investment Co Ltd  
6<sup>th</sup> Floor, The Headquarters Building  
No. 168 Xizang Middle Road  
Shanghai 200001, China

**ChinaWhys (Shanghai) Consulting Co Ltd**  
摄连咨询(上海)有限公司  
上海南京西路 1168 号  
中信泰富广场 35-107 号  
邮编: 200041

Dear Mr. Reilly,

**Proposed Investigation – Project Scorpion**

Further to the recent contacts between yourself and ChinaWhys Co Ltd (“ChinaWhys”), I have pleasure in submitting the following proposal for your consideration.

**About ChinaWhys**

ChinaWhys is an independent China-focused risk management practice providing discreet risk mitigation solutions, investigation, consulting and research services to corporate clients in matters of high sensitivity throughout Greater China and Asia. We operate through an extensive and discreet network of associates across China and elsewhere in the region.

We have conducted such services in China on behalf of large, medium and small western multinationals in numerous industries, as well as non-governmental organizations, chambers of commerce, and high wealth individuals.

**Project Name**

This prospective engagement has been codenamed “Project Scorpion”.

**Background**

Our understanding of this matter is based on a limited briefing and any error is regretted. We understand that GSK, listed on the London and New York bourses, is one of the leading global health companies involved in research and development of a broad range of innovative medicines and brands. Headquartered in the UK, GSK has offices in more than 115 countries and an extensive manufacturing network around 70 sites globally. In China GSK operates one R&D centre and six manufacturing sites making products in prescription medicines and vaccines. In

addition it also provides products to the China market covering a wide range of therapeutic drugs as well as consumer healthcare products.

Ms. Vivian Shi Wen ("Vivian") was director of central government affairs of GSK China, based in Shanghai. In December 2012, given the findings on her irregular expense claim records, GSK China and Vivian by mutual agreement terminated Vivian's employment contract with the company.

Regardless of the expense claim irregularities, Vivian had been suspected for some time of being the behind-the-scenes author of a smear campaign against GSK stretching over a period of about 14 months and involving at least 23 anonymous letters sent to government agencies around the country and several emails sent to GSK's top management.

The letters alleged that bribery is rife in GSK China sales and that the practice was endorsed by senior management. In response to the allegations, GSK conducted internal investigations but could not substantiate the allegations. GSK believes Vivian orchestrated these attacks on the company but it says it has no direct evidence of this.

In March 2013 an email was sent to GSK's CEO Andrew Witty and five other senior executives in the US and the UK, alleging that GSK China used its travel agent to funnel kickbacks to customers or doctors. In addition, attached to the email was a video recording of GSK China's president Mark Reilly, apparently filmed in his apartment. Security experts believe a camera had been secretly positioned on top of a TV set in his bedroom.

The clip was edited professionally in an effort to disguise the location, but it was obvious to Mark Reilly that the video was shot in his room. It is assumed the camera was installed when Dr. Reilly was away, and it had been removed by the time the email and clip were sent out.

GSK presumes the aim of this incident was to damage Reilly's reputation irretrievably and to prompt GSK to fire him. GSK reported the incident to local Chinese police (PSB) and Reilly relocated to a more secure residence with a surveillance camera fitted over his apartment door.

His travel schedule is widely known at the company, and it is assumed that someone must have leaked his schedule to Vivian or her accomplices or to some author of the incident.

GSK is concerned that Vivian may have local PSB contacts who could have helped to plant the camera in Reilly's room. It is also possible that she hired private investigators to do it.

Vivian is said to be very close to officials of the State Food and Drug Administration (SFDA) in Shanghai, the government agency which regulates pharmaceutical companies.

She is said to be married, with one daughter, and her husband is said to work for a university.

Since her departure from GSK, she is said to have been seeking employment with multinational pharmaceutical or health product manufacturers – without success up to date.

Vivian is said to be strongly disliked by her former GSK colleagues. Most people who used to work with her left the company.

In order to improve its understanding of the matter and in the interest of defending its reputation, GSK wishes to conduct a discreet information search into Vivian, her activities, track record with previous employers, and her political influence, to assess the potential risks that her activities may pose to GSK, and to gather any available evidence that Vivian orchestrated the smear campaign against GSK and Dr. Reilly.

### **Objective**

The objective of Project Scorpion is to assist GSK to mitigate the risks associated with the smear campaign through discreet investigative actions addressing the focal issues listed above.

### **Proposed Course of Action**

Based on the facts presented to us by GSK, it is now proposed to proceed as follows.

#### **■ *Collection and review of client information***

Before we commence our investigation, GSK will provide us with all necessary start-up information required to facilitate well-focused and economical inquiries, including:

- Full identifiers of Vivian Shi, including her full names in Chinese and English, CVs, HR data forms, ID number, copy of ID card, copy of business card, all known addresses, all known phone numbers, all known email addresses, all known social media platforms that she belongs to, copy of employment contract, recent photo, details of any known family members (possibly to be found in the emergency contacts section of her HR file), etc, to the best knowledge of GSK, if there is any.
- Details of employees who have worked with Vivian and the org chart which specifies the positions of these employees, and their contact details.
- Copies of any allegation emails in GSK's possession. Any such emails should be provided in the form of detached eml files in their original format so that we can attempt a trace analysis on them.
- A copy of Vivian's profile from *Weibo*, mentioned by GSK in our briefing.
- Names of SFDA officials with whom Vivian is known to be close and any other government agencies that Vivian was routinely in contact with in the course of her work.
- Full address of Mark Reilly's former residence where the camera was installed. Details of landlord. Details of building management and security department there.
- Any additional anecdotal or 'hearsay' information about the activities of the suspects and related entities and associates.

■ ***Phase 1 Investigation***

Once the information is received, we will thoroughly review the above start-up information and then initiate inquiries into Vivian and her contacts.

- Our analysts will conduct thorough desktop research in Chinese and English comprising searches of public and private online electronic resources, business databases, especially Chinese-language sources, on Vivian in order to gather all information about her that is available in open sources without alerting her, to build a profile and explore her social network, and to develop leads for our inquiries.
- We will aim to identify the security service firm which provides guard services to Reilly's former residence building and learn whether it has kept any CCTV security film from the period when the illicit video was shot (believed to be the first week of March 2013).
- We will conduct discreet inquiries with official agencies and knowledgeable contacts into Vivian and her family members in an effort to ascertain the strength of any political and governmental connections they may have.
- We will identify sources close to Vivian from her various past employments and discreetly approach them to gather further information about Vivian's connections with government and SFDA hierarchies, and to gather additional information about her personal behaviour, track record and past departures from employers.
- We will discreetly approach knowledgeable sources within the government and SFDA to obtain their view on the strength of any ties that Vivian could potentially use to harm GSK.
- We will also discreetly inquire into whether Vivian has close contacts with the Shanghai PSB, and whether it is possible that such PSB contacts could have helped to bug Reilly's apartment with the hidden camera.
- As far as is this is safely and technically possible, our contacts will be recorded.
- When conducting the above search and inquiry, we will use our best efforts to ensure that such actions will not alert Vivian or pose any harm to the GSK's decent relationship with government agencies.
- Upon completion of our inquiries we will provide a report containing our findings and any collected evidence.

***Potential Optional Follow-Up Phases***

While we always endeavor to complete such investigations as far as possible in a single round of inquiries, there are occasions when additional phases of inquiry or additional actions may be required in order close the loop on a complex matter. If required by GSK, such additional actions in this matter could potentially include some of the following:

- E-review of workplace PC and email data to search for additional leads and evidence.

- Orchestration of surveillance actions to identify activities and affiliations of the subject.
- Drill-down inquiries on particular parties and issues identified in the course of Phase 1.
- Related discreet inquiries in additional jurisdictions based on leads uncovered in Phase 1.
- Internal investigation comprising interviews with GSK personnel.

The scope and costs of any such additional actions would be negotiated and agreed with GSK separately from the Phase 1 outlined above, before any such additional actions are initiated.

#### **Caveat: Information Restrictions**

Please note that China has been undergoing a political leadership change this year and this is a period of political tension, with a tightening of control over information flow. We have seen sudden swings and arbitrary regulatory restrictions on the availability of certain documentary data in recent months such as company registration details and ownership, financials and other details, and personal data, in certain parts of the country. The nature, location, scope and timing of such regulatory restrictions when they occur are unpredictable. We would make our best efforts to complete the assignment by gathering all available information through legal means.

#### **Utilization of Findings**

Our findings are exclusively for the use of GSK and its legal advisers in assessing and mitigating business risk and not for publication or distribution to any other third party. Should GSK wish to use our findings in any legal proceedings, this could require additional work in collaboration with your legal counsel to package any legally admissible material for evidentiary purposes. The ChinaWhys name may not be revealed to third parties without our prior written consent, which will not be unreasonably withheld and which will be based upon our assessment of security risks posed to ChinaWhys and its personnel.

#### **Project Fees**

For Phase 1 of this investigation we will require a professional fee of RMB 220,000.

Our professional fees are quoted exclusive of PRC VAT, which will be applied to our invoices.

In addition to our professional fees, reasonable disbursements for travel, accommodation, registry and database charges, duty meals, etc, will be charged at cost. These out-of-pockets will not exceed the equivalent of 15% of our professional fees.

The fees for any subsequent phases or actions would be negotiated separately based on the scope of work anticipated.

#### **Conduct of the Assignment**

As information develops in the course of the project, new leads of inquiry may be identified in new jurisdictions or directions requiring additional work to be carried out. We will review such information with you to determine its relevance to the objectives and to assess whether any such new work should be conducted and further budget allocated. Any additional phase of the project would be defined and agreed in writing through these discussions.

**Reporting**

Upon completion of Phase 1, a report will be submitted to you. Before its submission any significant information that emerges during our inquiries will be communicated to you promptly. We estimate a completion period for Phase 1 of four working weeks. (The upcoming May Day public holiday in mainland China will interrupt our work for several days.)

**Non-Solicitation**

For a period of two years from the signing of this letter GSK shall not solicit, offer employment, hire, or offer assignments directly or indirectly to any employee or subcontractor or supplier of ChinaWhys, without the prior written consent of ChinaWhys. Also, GSK shall not attempt to entice, lure away or refer directly or indirectly any employee or subcontractor or supplier of ChinaWhys to any other third party.

**Terms of Business**

Other working conditions are as stated in the Consultancy Agreement between GSK and us (attached).

**Acceptance**

We much look forward to cooperating with you on this important project. Should the issues and terms set out in this proposal be acceptable, would you please sign and return a copy of this letter. We will be available to start work on receipt of payment of the invoice for the retainer fee.

Thank you for the opportunity to be of service to Client. If you would like to further clarify any of the matters raised in this document please contact me. We look forward to hearing from you at your convenience.

Yours sincerely,



Mr. Peter Humphrey  
Managing Director,  
ChinaWhys

Proposal has been accepted by:

Signature:

NAME:

Title:

Home / China / Society

## Foreigners nabbed for personal info trafficking

Updated: 2013-08-27 05:59

(Xinhua)

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SHANGHAI - Police in Shanghai have detained a foreign couple who were suspectedly involved in operating illegal research companies and trafficking personal information, police sources said on Monday.

Peter William Humphrey, a 57-year old British national, and Yu Ying Zeng, 60, who was an American and identified as Peter's wife, have been arrested by police on Aug 16, according to the police.

Investigation found that the couple illegally trafficked a huge amount of personal information on Chinese citizens to seek profits via registering so-called research companies in Hong Kong and Shanghai since 2003.

Among the 500 investigative reports seized by police, more than ten were found to have infringed on Chinese citizens' right of privacy, police said.

The personal information traded by the couple included residence addresses, family members, exit-entry information and real estate, according to police.

The couple have confessed to their criminal facts and apologized to the Chinese government, police said.

Police in Shanghai have arrested 126 people for illegal personal information trafficking and solved more than 140 related cases in the first 10 days of August.

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# The Fraud Examiner

## HOW FRAUD INVESTIGATION JUST GOT HARDER IN CHINA

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### *Exploring the Impact of China's clampdown on public records*

May 2013

By Peter Humphrey, CFE

Over the past 15 years, I have witnessed the gradual emergence of an investigation industry in China. It began from crude anti-counterfeit outfits and family investigation agencies and gradually extended to the more sophisticated areas of due diligence, fraud investigation and forensics, as well as compliance and FCPA investigations. In the same period, we saw increasing availability of what in most countries we call "public records," including company registration files, annual returns and some limited, but useful, personal data.

The availability of such records combined with a CFE's skill set of forensic accountants enabled anti-fraud professionals to do their job in a country where foreign investors feel at risk due to a high white-collar crime rate, a lack of transparency and strong cultural barriers in business operations.

The promising environment that evolved for the fight against fraud and bribery in company operations in China has suffered a major setback due to a sudden government action to suppress certain data contained in such records. Why has this U-turn happened, and what is its impact on anti-fraud work?

In January 2013, forensic and investigation firms -- and local law firms -- found that they or their search agents could no longer freely access records filed with the Administration of Industry and Commerce (AIC) bureaus around the country. The AIC registers, incorporates, inspects and regulates all companies in China, and collects their annual returns. These records, until recently accessible in full, contain useful data and documents relating to the birth, evolution and status of a company, names and personal details of shareholders, annual financial data and annual audit reports.

It is by examining these records in conjunction with a forensic accounting review that a CFE here can close the circle on a fraud -- for example, by proving that Mr. X, an employee of Company Z, has set up his own firm (and, by the way, with no physical existence) and inserted this phantom into the sales chain as part of a large-scale distribution fraud against his employer.

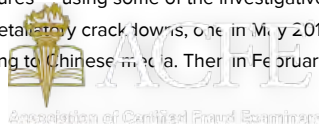
Or, it can enable a would-be investor considering buying shares in a Chinese company listed on Nasdaq to determine that the company has inflated its sales data and that its principals have actually been involved in a string of stock-listing frauds.

During 2011 and 2012, short-seller Muddy Waters not only shorted Chinese stocks (such as Sino Forest) that it had identified (possibly correctly) as fraudulent, it also published its findings on each firm in a manner viewed by authorities in Beijing as rabidly anti-Chinese, thus putting the Chinese Foreign Ministry on the back foot and unnecessarily provoking a government reaction. Soon after that, *Bloomberg* ran exposés on the business web and assets of a (now disgraced) Chinese Politburo member Mr. Bo Xi Lai and his wife, and then gave the family of China's new President-to-be Mr. Xi Jinping similar treatment. In a third such article, the *New York Times* threw oil on the fire in October with a detailed piece on the wealth of Premier Wen Jiabao's family.

Exhibit

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For a moment it appeared that these publishing adventures — using some of the investigative techniques of the forensic investigators, such as analysing AIC records — were making China's ruling elite wobble. In retaliation crack downs, one in May 2012 and one in January 2013, more than 1,000 local investigators and their alleged sources each time were detained, according to Chinese media. Then in February this year, the government issued strict new rules to restrict access to what it called "personal information."


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Critics describe this clampdown as an attempt to protect corrupt government officials from exposure. But as an anti-fraud worker in China serving purely corporate clients on corporate matters or in litigation support I find this a very dark day for due diligence and forensics work. I find this a step backwards that will make due diligence and catching fraudsters harder. We will have to be even more creative from now on.

As the recent disaster of a \$580 million fraud at a Chinese company acquired by Caterpillar shows, due diligence in China is a vital part of M&A for any sensible acquirer. If Caterpillar had done the kind of due diligence combining accounting with background investigation, retrieval of AIC records and discreet supporting inquiries, it might have spotted the fraud before doing the deal last year. But today, even if it wanted to take that approach, it would find it much harder to do as a result of the clampdown on public records.

Harbin Electric, a Chinese firm publicly-listed in the U.S. via reverse merger, i.e. a "backdoor listing," claimed in SEC filings that one of its largest clients in 2009 was a car seat maker to whom it sold motors, earning 10 percent of its revenue for the year, and that the A/R due from this client was \$10 million by that year's end. A discreet interview with a sales engineer working for the customer, however, revealed that the customer had bought just \$58,300 of goods between 2006 and 2007 and bought nothing else from Harbin Electric after that. This publicized case was an example of a widespread method of deception whereby Chinese firms exploited regulatory gaps and differences between Chinese company names and their English translations to file records and numbers in the U.S. that hugely differ from those they filed in China. For the U.S. audience such firms were faking revenue data in order to ramp up their share price in the U.S. market. Middlemen who took these companies abroad fabricated financial statements and got accounting firms to window-dress them, and supplied fake bank statements, fund transfer notes, bank drafts, delivery notes, etc. The brokers eager for these deals to be completed deliberately limited the due diligence scope as they would benefit from these listings going through regardless of any future losses to investors. In another example of this, we saw a rigged financial due diligence report done by "qualified accountants" engaged by a PE broker on a Chinese juice maker that was being groomed for listing in the U.S. It showed revenue packaged to come (ostensibly) from seven large customers, each contributing an uncannily similar 13 to 15 percent of the total, and A/R from three of them in identical figures. They had concocted the totals that they wanted to report, and simply divided it by seven.

At the same time that this skulduggery was going on in these cases, a financial institution which was trying to decide whether to invest in these firms engaged us to perform independent behind-the-scenes due diligence which included retrieval of records and returns filed by these companies locally in China, a review by forensic investigators, and a comparison with SEC filings. This way, they spotted the rat and avoided making potentially loss-making share investments. Following this year's clampdown on the release of financial data from AIC files, this is no longer possible.

With financial returns and personal identification data less available to help connect the dots, fraud investigation and due diligence in China must rely more on human source inquiries, both with related parties and with insiders (such as managers, sales agents, production staff, suppliers and so on) to ascertain that real business exists; and a forensic internal review, if circumstances allow it, in order to identify not only signs of irregularities but to drill down into their origins. The costs of this work will be well justified if they can prevent or detect large losses.

*Peter Humphrey is the founder and Managing Director of ChinaWhys, a forensics firm specialising in China matters. He is Founding President of the China chapters of the Association of Certified Fraud Examiners (ACFE). He is fluent in Chinese and has dealt with China and other Communist countries for 38 years. He can be contacted at [peter.humphrey@chinawhys.com](mailto:peter.humphrey@chinawhys.com)*

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## JUSTICE NEWS

Department of Justice  
Office of Public Affairs

FOR IMMEDIATE RELEASE

Monday, July 2, 2012

### **GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data**

#### **Largest Health Care Fraud Settlement in U.S. History**

Global health care giant GlaxoSmithKline LLC (GSK) agreed to plead guilty and to pay \$3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices, the Justice Department announced today. The resolution is the largest health care fraud settlement in U.S. history and the largest payment ever by a drug company.

GSK agreed to plead guilty to a three-count criminal information, including two counts of introducing misbranded drugs, Paxil and Wellbutrin, into interstate commerce and one count of failing to report safety data about the drug Avandia to the Food and Drug Administration (FDA). Under the terms of the plea agreement, GSK will pay a total of \$1 billion, including a criminal fine of \$956,814,400 and forfeiture in the amount of \$43,185,600. The criminal plea agreement also includes certain non-monetary compliance commitments and certifications by GSK's U.S. president and board of directors. GSK's guilty plea and sentence is not final until accepted by the U.S. District Court.

GSK will also pay \$2 billion to resolve its civil liabilities with the federal government under the False Claims Act, as well as the states. The civil settlement resolves claims relating to Paxil, Wellbutrin and Avandia, as well as additional drugs, and also resolves pricing fraud allegations.

"Today's multi-billion dollar settlement is unprecedented in both size and scope. It underscores the Administration's firm commitment to protecting the American people and holding accountable those who commit health care fraud," said James M. Cole, Deputy Attorney General. "At every level, we are determined to stop practices that jeopardize patients' health, harm taxpayers, and violate the public trust – and this historic action is a clear warning to any company that chooses to break the law."

"Today's historic settlement is a major milestone in our efforts to stamp out health care fraud," said Bill Corr, Deputy Secretary of the Department of Health and Human Services (HHS). "For a long time, our health care system had been a target for cheaters who thought they could make an easy profit at the expense of public safety, taxpayers, and the millions of Americans who depend on programs like Medicare and Medicaid. But thanks to strong enforcement actions like those we have announced today, that equation is rapidly changing."

Exhibit

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This resolution marks the culmination of an extensive investigation by special agents from HHS-OIG, FDA and FBI, along with law enforcement partners across the federal government. Moving forward, GSK will be subject to stringent requirements under its corporate integrity agreement with HHS-OIG; this agreement is designed to increase accountability and transparency and prevent future fraud and abuse. Effective law enforcement partnerships and fraud prevention are hallmarks of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which fosters government collaboration to fight fraud.

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### Criminal Plea Agreement

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Under the provisions of the Food, Drug and Cosmetic Act, a company in its application to the FDA must specify each intended use of a drug. After the FDA approves the product as safe and effective for a specified use, a company's promotional activities must be limited to the intended uses that FDA approved. In fact, promotion by the manufacturer for other uses – known as “off-label uses” – renders the product “misbranded.”

Paxil: In the criminal information, the government alleges that, from April 1998 to August 2003, GSK unlawfully promoted Paxil for treating depression in patients under age 18, even though the FDA has never approved it for pediatric use. The United States alleges that, among other things, GSK participated in preparing, publishing and distributing a misleading medical journal article that misreported that a clinical trial of Paxil demonstrated efficacy in the treatment of depression in patients under age 18, when the study failed to demonstrate efficacy. At the same time, the United States alleges, GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18. The United States further alleges that GSK sponsored dinner programs, lunch programs, spa programs and similar activities to promote the use of Paxil in children and adolescents. GSK paid a speaker to talk to an audience of doctors and paid for the meal or spa treatment for the doctors who attended. Since 2004, Paxil, like other antidepressants, included on its label a “black box warning” stating that antidepressants may increase the risk of suicidal thinking and behavior in short-term studies in patients under age 18. GSK agreed to plead guilty to misbranding Paxil in that its labeling was false and misleading regarding the use of Paxil for patients under 18.

Wellbutrin: The United States also alleges that, from January 1999 to December 2003, GSK promoted Wellbutrin, approved at that time only for Major Depressive Disorder, for weight loss, the treatment of sexual dysfunction, substance addictions and Attention Deficit Hyperactivity Disorder, among other off-label uses. The United States contends that GSK paid millions of dollars to doctors to speak at and attend meetings, sometimes at lavish resorts, at which the off-label uses of Wellbutrin were routinely promoted and also used sales representatives, sham advisory boards, and supposedly independent Continuing Medical Education (CME) programs to promote Wellbutrin for these unapproved uses. GSK has agreed to plead guilty to misbranding Wellbutrin in that its labeling did not bear adequate directions for these off-label uses. For the Paxil and Wellbutrin misbranding offenses, GSK has agreed to pay a criminal fine and forfeiture of \$757,387,200.

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Avandia: The United States alleges that, between 2001 and 2007, GSK failed to include certain safety data about Avandia, a diabetes drug, in reports to the FDA that are meant to allow the FDA to determine if a drug continues to be safe for its approved indications and to spot drug safety trends. The missing information included data regarding certain post-marketing studies, as well as data regarding two studies undertaken in response to European regulators' concerns about the cardiovascular safety of Avandia. Since 2007, the FDA has added two black box warnings to the Avandia label to alert physicians about the potential increased risk of (1) congestive heart failure, and (2) myocardial infarction (heart attack). GSK has agreed to plead guilty to failing to report data to the FDA and has agreed to pay a criminal fine in the amount of \$242,612,800 for its unlawful conduct concerning Avandia.

"This case demonstrates our continuing commitment to ensuring that the messages provided by drug manufacturers to physicians and patients are true and accurate and that decisions as to what drugs are prescribed to sick patients are based on best medical judgments, not false and misleading claims or improper financial inducements," said Carmen Ortiz, U.S. Attorney for the District of Massachusetts.

"Patients rely on their physicians to prescribe the drugs they need," said John Walsh, U.S. Attorney for Colorado. "The pharmaceutical industries' drive for profits can distort the information provided to physicians concerning drugs. This case will help to ensure that your physician will make prescribing decisions based on good science and not on misinformation, money or favors provided by the pharmaceutical industry."

### Civil Settlement Agreement

As part of this global resolution, GSK has agreed to resolve its civil liability for the following alleged conduct: (1) promoting the drugs Paxil, Wellbutrin, Advair, Lamictal and Zofran for off-label, non-covered uses and paying kickbacks to physicians to prescribe those drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex; (2) making false and misleading statements concerning the safety of Avandia; and (3) reporting false best prices and underpaying rebates owed under the Medicaid Drug Rebate Program.

**Off-Label Promotion and Kickbacks:** The civil settlement resolves claims set forth in a complaint filed by the United States alleging that, in addition to promoting the drugs Paxil and Wellbutrin for unapproved, non-covered uses, GSK also promoted its asthma drug, Advair, for first-line therapy for mild asthma patients even though it was not approved or medically appropriate under these circumstances. GSK also promoted Advair for chronic obstructive pulmonary disease with misleading claims as to the relevant treatment guidelines. The civil settlement also resolves allegations that GSK promoted Lamictal, an anti-epileptic medication, for off-label, non-covered psychiatric uses, neuropathic pain and pain management. It further resolves allegations that GSK promoted certain forms of Zofran, approved only for post-operative nausea, for the treatment of morning sickness in pregnant women. It also includes allegations that GSK paid kickbacks to health care professionals to induce them to promote and prescribe these drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex. The United States alleges that this conduct caused false claims to be submitted to federal health care programs.

GSK has agreed to pay \$1.043 billion relating to false claims arising from this alleged conduct. The federal share of this settlement is \$832 million and the state share is \$210 million.

This off-label civil settlement resolves four lawsuits pending in federal court in the District of Massachusetts under the qui tam, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the United States and share in any recovery.

**Avandia:** In its civil settlement agreement, the United States alleges that GSK promoted Avandia to physicians and other health care providers with false and misleading representations about Avandia's safety profile, causing false claims to be submitted to federal health care programs. Specifically, the United States alleges that GSK stated that Avandia had a positive cholesterol profile despite having no well-controlled studies to support that message. The United States also alleges that the company sponsored programs suggesting cardiovascular benefits from Avandia

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therapy despite warnings on the FDA-approved label regarding cardiovascular risks. GSK has agreed to pay \$657 million relating to false claims arising from misrepresentations about Avandia. The federal share of this settlement is \$508 million and the state share is \$149 million.

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Price Reporting: GSK is also resolving allegations that, between 1994 and 2003, GSK and its corporate predecessors reported false drug prices, which resulted in GSK's underpaying rebates owed under the Medicaid Drug Rebate Program. By law, GSK was required to report the lowest, or "best" price that it charged its customers and to pay quarterly rebates to the states based on those reported prices. When drugs are sold to purchasers in contingent arrangements known as "bundles," the discounts offered for the bundled drugs must be reallocated across all products in the bundle proportionate to the dollar value of the units sold. The United States alleges that GSK had bundled sales arrangements that included steep discounts known as "nominal" pricing and yet failed to take such contingent arrangements into account when calculating and reporting its best prices to the Department of Health and Human Services. Had it done so, the effective prices on certain drugs would have been different, and, in some instances, triggered a new, lower best price than what GSK reported. As a result, GSK underpaid rebates due to Medicaid and overcharged certain Public Health Service entities for its drugs, the United States contends. GSK has agreed to pay \$300 million to resolve these allegations, including \$160,972,069 to the federal government, \$118,792,931 to the states, and \$20,235,000 to certain Public Health Service entities who paid inflated prices for the drugs at issue.

Except to the extent that GSK has agreed to plead guilty to the three-count criminal information, the claims settled by these agreements are allegations only, and there has been no determination of liability.

"This landmark settlement demonstrates the Department's commitment to protecting the American public against illegal conduct and fraud by pharmaceutical companies," said Stuart F. Delery, Acting Assistant Attorney General for the Justice Department's Civil Division. "Doctors need truthful, fair, balanced information when deciding whether the benefits of a drug outweigh its safety risks. By the same token, the FDA needs all necessary safety-related information to identify safety trends and to determine whether a drug is safe and effective. Unlawful promotion of drugs for unapproved uses and failing to report adverse drug experiences to the FDA can tip the balance of those important decisions, and the Justice Department will not tolerate attempts by those who seek to corrupt our health care system in this way."

#### Non-monetary Provisions and Corporate Integrity Agreement

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In addition to the criminal and civil resolutions, GSK has executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). The plea agreement and CIA include novel provisions that require that GSK implement and/or maintain major changes to the way it does business, including changing the way its sales force is compensated to remove compensation based on sales goals for territories, one of the driving forces behind much of the conduct at issue in this matter. Under the CIA, GSK is required to change its executive compensation program to permit the company to recoup annual bonuses and long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. GSK may recoup monies from executives who are current employees and those who have left the company. Among other things, the CIA also requires GSK to implement and maintain transparency in its research practices and publication policies and to follow specified policies in its contracts with various health care payors.

"Our five-year integrity agreement with GlaxoSmithKline requires individual accountability of its board and executives," said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. "For

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example, company executives may have to forfeit annual bonuses if they or their subordinates engage in significant misconduct, and sales agents are now being paid based on quality of service rather than sales targets.”

“The FDA Office of Criminal Investigations will aggressively pursue pharmaceutical companies that choose to put profits before the public’s health,” said Deborah M. Autor, Esq., Deputy Commissioner for Global Regulatory Operations and Policy, U.S. Food and Drug Administration. “We will continue to work with the Justice Department and our law enforcement counterparts to target companies that disregard the protections of the drug approval process by promoting drugs for uses when they have not been proven to be safe and effective for those uses, and that fail to report required drug safety information to the FDA.”

“The record settlement obtained by the multi-agency investigative team shows not only the importance of working with our partners, but also the importance of the public providing their knowledge of suspect schemes to the government,” said Kevin Perkins, Acting Executive Assistant Director of the FBI’s Criminal, Cyber, Response and Services Branch. “Together, we will continue to bring to justice those engaged in illegal schemes that threaten the safety of prescription drugs and other critical elements of our nation’s healthcare system.”

“Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior,” said Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management. “Today’s settlement reminds the pharmaceutical industry that they must observe those standards and reflects the commitment of Federal law enforcement organizations to pursue improper and illegal conduct that places health care consumers at risk.”

“Today’s announcement illustrates the efforts of VA OIG and its law enforcement partners in ensuring the integrity of the medical care provided our nation’s veterans by the Department of Veterans Affairs,” said George J. Opfer, Inspector General of the Department of Veterans Affairs. “The monetary recoveries realized by VA in this settlement will directly benefit VA healthcare programs that provide for veterans’ continued care.”

“This settlement sends a clear message that taking advantage of federal health care programs has substantial consequences for those who try,” said Rafael A. Medina, Special Agent in Charge of the Northeast Area Office of Inspector General for the U.S. Postal Service. “The U.S. Postal Service pays more than one billion dollars a year in workers’ compensation benefits and our office is committed to pursuing those individuals or entities whose fraudulent acts continue to unfairly add to that cost.”

#### A Multilateral Effort

The criminal case is being prosecuted by the U.S. Attorney’s Office for the District of Massachusetts and the Civil Division’s Consumer Protection Branch. The civil settlement was reached by the U.S. Attorney’s Office for the District of Massachusetts, the U.S. Attorney’s Office for the District of Colorado and the Civil Division’s Commercial Litigation Branch. Assistance was provided by the HHS Office of Counsel to the Inspector General, Office of the General Counsel-CMS Division and FDA’s Office of Chief Counsel as well as the National Association of Medicaid Fraud Control Units.

This matter was investigated by agents from the HHS-OIG; the FDA's Office of Criminal Investigations; the Defense Criminal Investigative Service of the Department of Defense; the Office of the Inspector General for the Office of Personnel Management; the Department of Veterans Affairs; the Department of Labor; TRICARE Program Integrity; the Office of Inspector General for the U.S. Postal Service and the FBI.

This resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by Attorney General Eric Holder and Kathleen Sebelius, Secretary of HHS. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. Over the last three years, the department has recovered a total of more than \$10.2 billion in settlements, judgments, fines, restitution, and forfeiture in health care fraud matters pursued under the False Claims Act and the Food, Drug and Cosmetic Act.

Court documents related to today's settlement can be viewed online at [www.justice.gov/opa/gsk-docs.html](http://www.justice.gov/opa/gsk-docs.html).

Related Materials:

[Remarks by the Deputy Attorney General James M. Cole at the GSK Press Conference](#)

[Remarks by Acting Assistant Attorney General for the Civil Division Stuart F. Delery at the GSK Press Conference](#)

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12-842

Civil Division

Topic:  
Consumer Protection

Updated May 22, 2015

**CORPORATE INTEGRITY AGREEMENT**  
**BETWEEN THE**  
**OFFICE OF INSPECTOR GENERAL**  
**OF THE**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**AND**  
**GLAXOSMITHKLINE LLC**

**I. PREAMBLE**

GlaxoSmithKline LLC (GSK) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements).

Contemporaneously with this CIA, GSK is entering into Settlement Agreements with the United States. GSK will also enter into settlement agreements with various States (State Settlement Agreements) and GSK's agreement to this CIA is a condition precedent to those agreements. Effective October 26, 2010, GSK entered into a Settlement Agreement with the United States to resolve allegations regarding certain drugs manufactured at SB Pharmco's Cidra, Puerto Rico facility.

Prior to the Effective Date of this CIA (as defined below), GSK and GSK Affiliates (as defined below in Section II.C.10) established a worldwide voluntary compliance program designed to address the companies' operations globally. In the United States, the compliance program is designed to address, among other things, compliance with Federal health care program and FDA requirements (Compliance Program).

GSK shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. GSK may modify its Compliance Program as appropriate, but, at a minimum, GSK shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

GlaxoSmithKline LLC  
Corporate Integrity Agreement

## **II. TERM AND SCOPE OF THE CIA**

A. Unless otherwise specified, the period of the compliance obligations assumed by GSK and its Affiliates under this CIA shall be five reporting periods, as defined below. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. The first Reporting Period shall be from the Effective Date through December 31, 2013. The second and subsequent Reporting Periods shall be from January 1 through December 31 of each of the subsequent four calendar years.

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) GSK’s final Annual Report; or (2) any additional materials submitted by GSK pursuant to OIG’s request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. “Covered Persons” includes:

a. all owners of GlaxoSmithKline PLC who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading or in connection with the operation of employee long term incentive plans) and all directors of GlaxoSmithKline PLC;

b. all employees of GSK or any GSK Affiliate who are engaged in or supervise personnel who are engaged in any of the Covered Functions (as defined below in Section II.C.7); and

c. contractors, subcontractors, agents and other persons (including, but not limited to, third party vendors who provide services relating to the Covered Functions) who perform any of the Covered Functions on behalf of GSK or any GSK Affiliate and who in that capacity either: (i) interact directly with health care professionals (HCPs), healthcare institutions (HCIs), or consumers; or (ii) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term Covered Persons does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “Relevant Covered Persons” includes all Covered Persons who engage in Covered Functions or who supervise Covered Persons who engage in Covered Functions.
3. “Government Reimbursed Products” refers to all GSK prescription<sup>1</sup> pharmaceutical products that are marketed or sold by GSK (including by its Pharma, Stiefel, Vaccines, and Oncology division) in the United States (or pursuant to contracts with the United States) that are reimbursed by Federal health care programs.
4. The term “Promotional Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to any applicable review committees, including GSK’s Copy Approval Team (CAT).
5. The term “Product Related Functions” includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to HCPs and HCIs about Government Reimbursed Products, including those functions relating to GSK’s CAT or other applicable review committee(s) and activities by GSK’s North America Medical Affairs department (Medical Affairs); (b) contracting with HCPs and HCIs in the United States to conduct post-marketing clinical trials, investigator sponsored studies (ISSs), and other post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and

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<sup>1</sup> GSK represents that its Consumer Healthcare business unit shall not market, detail, or otherwise promote prescription pharmaceutical products for the duration of the CIA. Should the Consumer Healthcare business unit begin to do so, it shall become subject to the terms of the CIA.

disclosure of articles or study results relating to post-marketing clinical trials and other post-marketing studies for Government Reimbursed Products (including studies of investigational and other uses and indications outside the currently approved uses and conditions of use); and (d) activities related to the submission of information about Government Reimbursed Products to compendia (such as DrugDex or other compendia of information about Government Reimbursed Products as defined below in Section III.B.3.t.)

6. The term “Payer Related Functions” refers to activities of GSK’s Policy, Payers and Vaccines (PPV) Unit and includes Promotional Functions and Product Related Functions as they relate to interactions between GSK and entities that provide a drug health benefit program for Government Reimbursed Products, including but not limited to government payers (e.g., Medicaid and Medicare) or individuals or entities under contract with or acting on behalf of government payers and commercial health plans (collectively referred to as “Payers”). Payer Related Functions also includes interactions with Payers related to formulary placement, supplemental rebate agreements, and other types of rebate agreements.
7. The term “Covered Functions” refers to “Promotional Functions,” “Product Related Functions,” and “Payer Related Functions” collectively.
8. The term “Third Party Educational Activity” shall mean any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by GSK, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.
9. The term “Third Party Personnel” shall mean employees of entities with whom GSK currently has, or in the future does, enter into agreements to promote or co-promote a Government Reimbursed Product or to engage in joint promotional activities relating to such a product. GSK represents that: (1) the Third Party Personnel are employed by independent entities other than GSK; (2) GSK does not control Third Party Personnel; and (3) it would be commercially impracticable to

compel the compliance of Third Party Personnel with the requirements set forth in this CIA. GSK agrees to promote compliance by Third Party Personnel with Federal health care program requirements and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.8, and V.B.4 related to Third Party Personnel. Provided that GSK complies with the requirements of Sections III.B.2, V.A.8, and V.B.4, GSK shall not be required to fulfill the remaining CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

10. The term “GSK Affiliate” shall mean GlaxoSmithKline PLC and any other entity (other than GlaxoSmithKline LLC) that is majority owned or controlled, directly or indirectly, by GlaxoSmithKline PLC and whose employees or contractors perform Covered Functions.

D. Appendix D to the CIA sets forth the obligations to which GSK and its Affiliates agree relating to manufacturing operations in connection with the settlement regarding the Cidra facility reference above in the Preamble. To the extent that certain general provisions and obligations are not specifically addressed in Appendix D, the terms of this CIA shall apply to CGMP Activities, Manufacturing Covered Persons, and to GSK and its Affiliates as specified herein.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

GSK shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Compliance Responsibilities of Certain GSK Employees and the Board of Directors.**

1. *Compliance Officer.* Prior to the Effective Date, GSK appointed an individual to serve as Vice President and Compliance Officer for its North America Pharma division (Compliance Officer). GSK shall maintain a Compliance Officer for the term of the CIA. During the term of this CIA, the Compliance Officer shall be authorized to oversee compliance with Federal health care program and FDA requirements and with the requirements of this CIA. The Compliance Officer is, and shall continue to be, responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health

care program and FDA requirements. The Compliance Officer shall be a member of senior management of GSK, and shall report directly to the Senior Vice President for Governance, Ethics, and Assurance of GlaxoSmithKline PLC who, in turn, reports to the Chief Executive Officer of GlaxoSmithKline PLC. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of GlaxoSmithKline PLC or any authorized committee thereof (hereinafter, “the Board”), and shall be authorized to report on such matters to the Board at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by GSK as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer’s ability to perform the duties outlined in this CIA.

GSK shall report to OIG, in writing, any change in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer’s ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, GSK formed compliance committee known as the NA Pharma Risk Management & Compliance Board (hereafter “Compliance Committee”) which, in conjunction with the Compliance Officer, assists in the implementation and enhancement of the Compliance Program. GSK shall continue the Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as such as legal, Medical Affairs, regulatory affairs, sales, marketing, human resources, research and development, global manufacturing quality control, and operations.) In addition, GSK’s Audit function provides regular reports to the Compliance Committee. The Compliance Officer and the President of GSK shall co-chair the Compliance Committee. The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the GSK’s risk areas and shall oversee monitoring of internal and external compliance-related audits and investigations). The Compliance Committee shall meet at least quarterly.

GSK shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance

Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* The Board shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board shall, at a minimum, be responsible for the following:

a. The Board shall meet at least quarterly to review and oversee GSK's Compliance Program, including but not limited to the performance of the Compliance Officer and other compliance personnel. The Board shall evaluate the effectiveness of the Compliance Program, including, at a minimum, by receiving updates about the activities of the Compliance Officer and other compliance personnel and updates about adoption and implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with applicable Federal health care program and FDA requirements.

b. For each Reporting Period of the CIA, the Board shall adopt a resolution, signed by each individual member of the Board, summarizing its review and oversight of GSK's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board of Directors has made a reasonable inquiry into the operations of GSK's Compliance Program as applicable to the CIA (including its Appendices) for the time period **[insert time period]**, including the performance of the Compliance Officer and the compliance personnel who are Covered Persons under this CIA. The Board has concluded that, to the best of its knowledge, GSK has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at GSK.

GSK shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Deputy Compliance Officers.* Prior to the Effective Date, GSK appointed Deputy Compliance Officers (DCOs) for each U.S. Pharma commercial business unit and for NA Pharma Medical Affairs, and GSK shall maintain the DCOs for the term of the CIA. Each DCO shall be a member of senior management of his/her respective business unit(s) and shall report directly to the Compliance Officer. The DCOs shall be responsible for working together with the Compliance Officer to oversee the development and implementation of policies, procedures, and practices designed to ensure business unit compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. Any noncompliance job responsibilities of the DCOs shall be limited and shall not interfere with each DCO's ability to perform the duties outline in this CIA.

5. *Integrity Champions.* Prior to the Effective Date, GSK implemented a program through which indentified individuals serve as Integrity Champions within each U.S. Pharma commercial business unit. Each individual selected to be an Integrity Champion shall be at least a manager within his/her respective business unit, and the responsibilities undertaken as an Integrity Champion shall be in addition to the individuals' existing management responsibilities. Integrity Champions shall be responsible for facilitating local implementation of, and adherence to, GSK policies and procedures, Federal health care program and FDA requirements, and the requirements of this CIA. Integrity Champions shall meet with their respective DCO on a regular basis. The performance of Integrity Champions, as such, will be a factor in their annual performance reviews.

6. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain GSK officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: President, GSK; the heads of the U.S. Pharma commercial business units; Chairman, Research and Development; Vice President, Strategic, Planning and Operations; Senior Vice President, NA Medical Affairs; President, Pharmaceuticals Research and Development; President, Vaccines; and Vice

President, Stiefel North America Dermatology, and, to the extent that a business unit performs Covered Functions and is not covered by the certification of one of the above-listed individuals, such other executives, vice-presidents, and directors of business units as would be necessary to ensure that there is a Certifying Employee from each such business unit.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the \_\_\_\_\_ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and GSK policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the \_\_\_\_\_ [insert name of department or functional area] of GSK is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a conclusion in the certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

#### B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, GSK developed and implemented a written Code of Conduct. Within 120 days after the Effective Date, GSK shall distribute the written Code of Conduct to all Covered Persons. GSK shall make adherence to the Code of Conduct an element in evaluating the performance of all employees who are Covered Persons. The Code of Conduct includes, or within 120 days after the Effective Date shall be revised to address the following:

- a. GSK’s commitment to full compliance with all Federal health care program requirements and FDA requirements, including its

commitment to comply with all requirements relating to the Covered Functions;

b. GSK's requirement that all of its Covered Persons shall be expected to comply with all applicable Federal health care program requirements, FDA Requirements, and with GSK's own Policies and Procedures;

c. GSK's requirement that all Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by GSK, suspected violations of any Federal health care program requirements, FDA requirements, or of GSK's own Policies and Procedures;

d. the personal obligations of each Covered Person to comply with Federal health care program requirements, FDA requirements, and GSK's Policies and Procedures; and

e. the right of all individuals to use the Disclosure Program described in Section III.F, and GSK's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 120 days after the Effective Date, each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

GSK shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Third Party Personnel.* Within 120 days after the Effective Date and annually thereafter by the anniversary of the Effective Date, GSK shall send a letter to each entity employing Third Party Personnel. The letter shall describe GSK's obligations under the CIA and its commitment to full compliance with all Federal health care program requirements and FDA requirements. The letter shall include a description of GSK's Compliance Program. GSK shall attach a copy of its Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of GSK's Code of Conduct and a description of GSK's Compliance Program available to its employees who meet the definition of Third Party Personnel as set forth in Section II.C.9; or (b) represent to GSK that it has and enforces a substantially comparable set of code of conduct and Compliance Program for its employees who meet the definition of Third Party Personnel as set forth in Section II.C.9.

3. *Policies and Procedures.* To the extent not already accomplished, GSK shall implement written policies and procedures regarding the operation of the Compliance Program and GSK's compliance with Federal health care program and FDA requirements (Policies and Procedures). At a minimum, the Policies and Procedures must address the following:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in compliance with all applicable FDA requirements;
- c. appropriate ways to conduct Product Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in compliance with all applicable FDA requirements;
- d. appropriate ways to conduct Payer Related Functions in compliance with all applicable Federal health care program

requirements, including but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)); the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); applicable FDA requirements; and applicable state laws. During the term of the CIA, the Policies and Procedures shall be consistent with GSK's US Commercial Practices Policy regarding "Administration of Contracts with Payers."

- e. the materials and information that may be distributed by GSK sales personnel about Government Reimbursed Products and the manner in which GSK sales personnel respond to requests for information about non-FDA approved (or "off-label") uses of Government Reimbursed Products. These Policies and Procedures shall require that sales personnel may not engage in off-label promotion (directly or indirectly) and must refer all requests for information about off-label uses of Government Reimbursed Products to Medical Affairs;
- f. the materials and information that may be distributed by GSK personnel from the PPV Unit and the manner in which PPV personnel respond to requests for information about off-label uses of Government Reimbursed Products. These Policies and Procedures shall require that all requests for information about off-label uses of Government Reimbursed Products be referred to Medical Affairs (i.e., Medical Information Scientists (MISs), Medical Science Liaisons (MSLs), and/or Health Outcome Liaisons (HOLs));
- g. the materials and information (including product information and product dossiers about Government Reimbursed Products) that may be distributed by Medical Affairs and the mechanisms through, and manner in which, Medical Affairs receives and responds to requests for information from an HCP or another individual or entity about off-label uses of GSK's Government Reimbursed Products; the form and content of information disseminated by GSK in response to such requests; and the internal review and approval process for the information disseminated. These Policies and Procedures shall require that

GSK sales personnel obtain a signature from the medical professional who verbally requested the written information confirming what information was requested and the request was unsolicited.

The Policies and Procedures shall include a requirement that Medical Affairs develop a database (“Inquiries Database”) to track all requests for information about Government Reimbursed Products to Medical Affairs. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about GSK’s products: (1) date of Inquiry; (2) form of Inquiry (e.g., fax, phone, etc.); (3) name of the requesting HCP, HCI, or other individual or entity; (4) nature and topic of request (including exact language of the Inquiry if made in writing); (5) an evaluation of whether the Inquiry relates to information about an off-label use for the product; (6) nature/form of the response from GSK (including a record of the materials provided to the HCP or HCI in response to the request); and (7) the name of the GSK representative who called on or interacted with the HCP, customer, or HCI, if known;

- h. the materials and information that may be distributed or made available by GSK through social media and/or through direct-to-consumer advertising. These policies and procedures shall be designed to ensure that GSK’s activities in this area and the information distributed or made available complies with all applicable Federal health care program and FDA requirements, and have been reviewed and approved by GSK before they are disseminated;
- i. the manner and circumstances under which medical personnel from Medical Affairs interact with or participate in meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to unsolicited requests about off-label indications of Government Reimbursed Products;

- j. the development, implementation, and review of target plans for sales personnel and other GSK personnel who promote and sell Government Reimbursed Products (Target Plans). For each Government Reimbursed Product, the Policies and Procedures shall require that GSK review Target Plans for the product and the bases upon, and circumstances under which HCPs and HCIs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the Target Plans. The Policies and Procedures shall also require that GSK modify the Target Plans as necessary to ensure that GSK is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The Target Plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;
- k. the development, implementation, and review of policies and procedures (including excluded specialties lists) for the distribution of samples of, or coupons or vouchers for, Government Reimbursed Products (collectively “Sample Distribution Policies and Procedures”). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples, coupons, or vouchers from GSK. GSK shall modify the Sample Distribution Policies and Procedures as necessary to ensure that GSK is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements;
- l. consultant or other fee-for-service arrangements entered into with HCPs or HCIs relating to Covered Functions (including, but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events

and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and shall include requirements about the content and circumstances of such arrangements and events. The Policies and Procedures shall require that compensation be based on fair market value, include caps on the total amount of payment that may be provided annually, and that HCPs who sit on formulary boards or develop clinical guidelines are required to disclose their relationship with GSK;

- m. programs to educate sales personnel, including but not limited to presentations by HCPs at sales meetings and experience-based learning activities, if any. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;
- n. sponsorship or funding of grants to healthcare-related organizations and donations to community partners in the United States (including support of any educational programs they conduct for non-HCP audiences). These Policies and Procedures shall be designed to ensure that GSK's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements. In addition, the Policies and Procedures continue to limit the situations in which GSK shall make grants and donations and shall state that GSK does not provide funding in order to influence the use of GSK products or services;
- o. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.8 above. These Policies and Procedures shall be designed to ensure that any GSK funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements. Prior to the

Effective Date of the CIA, GSK implemented policies restricting funding for Third Party Educational Activity to a limited number of specific types of entities (i.e., academic medical centers and their affiliated teaching and patient care institutions and professional medical associations that represent HCPs responsible for the delivery of patient care). These Policies and Procedures prohibit funding for independent medical education by commercial providers. During the term of the CIA, the Policies and Procedures shall continue to require that GSK provide funding for Third Party Educational Activity in accordance with its Policies and Procedures and practices outlined in this Section III.B.3.o and below in Section III.M.4.

The Policies and Procedures shall also require that: (1) GSK disclose its financial support of the Third Party Educational Activity and, to the extent feasible consistent with subsection III.B.3.o.4 below, any financial relationships with faculty, speakers, or organizers at such Activity; (2) as a condition of funding, the third party shall agree to disclose GSK's financial support of the Third Party Educational Activity and to require faculty, speakers, or organizers at such Activity to disclose any financial relationship with GSK; (3) the Third Party Educational Activity have an educational focus; (4) the content, organization, and operation of the Third Party Educational Activity (including the faculty, educational methods, materials, and venue) be independent of GSK's control; (5) GSK support only Third Party Educational Activity that is non-promotional in tone/nature; and (6) GSK's support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Third Party Educational Activity that is fair, balanced, accurate and not misleading;

- p. review of promotional materials and information intended to be disseminated outside GSK by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during GSK's review and approval process and are elevated when appropriate. The Policies and

Procedures shall be designed to ensure that such materials and information comply with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall require that: (1) applicable review committees (including the overall Copy Approval Team (CAT) and the CAT for each product) review all promotional materials prior to the distribution or use of such materials; (2) GSK's copy review and approval process ensure that FDA communications relevant to the product are considered and appropriately reflected in promotional materials and in a copy approval repository maintained by each CAT; and that (3) deviations from the standard review committee practices and protocols (including timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up;

- q. sponsorship, funding of, and disclosures relating to Product Related Functions. These Policies and Procedures shall be designed to ensure that GSK's funding, sponsorship, and disclosure complies with all applicable Federal health care program and FDA requirements;
- r. compensation (including through salaries, bonuses, or other means) for Covered Persons. These Policies and Procedures shall: (1) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of GSK's Government Reimbursed Products; and (2) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate off-label promotion of Government Reimbursed Products.

GSK represents that, prior to the Effective Date, it implemented a program in the United States to eliminate incentive compensative based on territory/individual level sales goals for prescriber-facing sales personnel (e.g., sales representatives) and their direct managers (Patient First Program). The Patient First Program is described in more detail below in Section III.H. GSK shall

continue its Patient First Program, or a substantially equivalent program, during the term of the CIA.

- s. GSK's right to recoup or cause the forfeiture of annual performance pay of GSK employees and Covered Executives if certain triggering events relating to misconduct by the employees or executives occur;
- t. the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter "Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (e.g., any changes based on GSK's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia.) The Policies and Procedures shall include a requirement that GSK conduct an annual review of all arrangements, processing fees, or other payments or financial support (if any) provided by GSK to any Compendia. GSK U.S. compliance personnel or other appropriately trained GSK personnel who are independent from the functional unit being reviewed shall be involved in this review;
- u. sponsorship by GSK of human subject research of Government Reimbursed Products (i.e., post-marketing clinical trials and post-marketing studies (collectively, "GSK-Sponsored Research")), and support by GSK of investigator-sponsored studies of Government Reimbursed Products (ISSs) (collectively, GSK-Sponsored Research and ISSs shall be referred to as "Research"), including the decision to provide financial or other support for Research; the manner in which Research support is provided; the publication of information about the Research, including the publication of information about the Research results and trial outcomes, and uses made of publications relating to Research;

Policies/Procedures regarding Sponsorship or Support of Studies Involving Government Reimbursed Products: GSK represents that it requires Research to be approved by its medical and/or research organizations. Under GSK's current policies and procedures, sales, marketing, or other commercial personnel may not participate in the design, conduct, or publication of GSK-Sponsored Research, with limited exceptions relating to non-interventional health outcomes studies (for which a relevant GSK medical group has oversight). GSK also represents that its human subject research and any resulting publications are intended to foster increased understanding of scientific, clinical or medical issues. To the extent not already accomplished, GSK shall require as a condition of its funding that all researchers disclose in any publication of Research, GSK's support and any financial interest the researcher may have in GSK.

Posting of Study Results and Protocols/Registry of Studies: GSK represents that, prior to the Effective Date, it developed a Clinical Study Register on which it posts, within a specified number of months from study completion and with rare exception, summary results from all GSK-Sponsored interventional Research studies of Government Reimbursed Products; and from GSK-Sponsored observational studies designed to inform the safety, efficacy or effectiveness, including cost-effectiveness, of Government Reimbursed Products; and from GSK-Sponsored meta-analyses and pooled analyses designed to inform appropriate, effective or safe use of Government Reimbursed Products. In addition, GSK posts summaries of its protocols for the studies and analyses described in the preceding sentence (including amendments that change the content of the summary) in its Register. GSK shall continue these practices throughout the term of the CIA.

In addition, GSK represents that it has established policies, systems, and practices to publish results from and information about discontinued studies on its Clinical Register, including the fact that the study terminated early. GSK shall continue these practices throughout the term of the CIA.

GSK represents that it registers summary results from all applicable GSK-sponsored clinical trials of GSK products and reports results of such clinical trials on the National Institutes of Health (NIH) sponsored website ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) in compliance with all Federal requirements. GSK shall continue to comply with Federal requirements or other applicable requirements relating to the registration and results reporting of clinical studies throughout the term of this CIA. In addition, if there is a change in Federal requirements or other applicable requirements relating to registration and results reporting of clinical study information, GSK shall fully comply with such requirements.

Publication of Study Results: GSK represents that it generally seeks publication of the results of all GSK-Sponsored interventional Research in peer-reviewed, searchable journals and imposes specified timeframes for the drafting and submission of manuscripts following completion of a study. For purposes of these publication requirements, GSK's publication policy includes certain GSK-Sponsored observational Research studies and certain GSK-Sponsored meta-analyses and pooled analyses.

In addition, GSK represents that it has established policies and "operating practices" governing scientific engagement, which included detailed directions regarding publications. Among other things, the operating practices require the implementation of data dissemination plans that establish prospective publication strategies for GSK-Sponsored Research and address requirements for appropriateness, accuracy, and balance in publications of GSK-Sponsored Research. In all publications about GSK-Sponsored Research, GSK shall acknowledge its role as the funding source.

In addition, GSK represents that it has established policies, systems, and practices designed to ensure that adverse event data is properly reported to the FDA. In addition, GSK requires investigators to report study-related information and data,

including data about adverse events before receiving final payment from GSK.

The standards, policies, and practices described above shall hereafter be referred to collectively as the “Research and Publication Practices.” GSK shall maintain its Research and Publication Practices (or standards and practices substantially equivalent to those set forth above) for studies initiated or completed after the Effective Date for the term of the CIA. To the extent that GSK intends to materially change these Research and Publication Practices, it shall notify the OIG about the change 30 days in advance of the effective date of the change;

- v. authorship of journal articles or other publications about GSK-Sponsored Research or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all financial relationships between the author and GSK, the identification of all authors or contributors (including professional writers) associated with a given publication, and that research results be made available to each author or contributor.

Authorship Requirements: GSK represents that it requires all authors of journal articles about GSK-Sponsored Research to adhere to International Committee of Medical Journal Editors (ICMJE) requirements regarding authorship except when a particular journal requires an alternative procedure. In addition, GSK requires all authors of articles on GSK-Sponsored Research to disclose any GSK financial support for the study and any financial relationship with GSK (including any financial interest the author may have in GSK or a GSK product). In addition, GSK represents that individuals may be considered an “author” on a GSK publication of GSK-Sponsored Research only if the individual has made substantial contributions to the study and has given final approval to the version of the publication ultimately published.

GSK shall require that its employees and medical writing contractors complete certain certification as to any GSK publication of GSK-Sponsored Research on which the individual is listed as an author or contributor. The standards, policies and practices described above shall be referred to collectively as “Authorship-Related Practices”; and

- w. disciplinary policies and procedures for violations of GSK’s Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 150 days after the Effective Date, the Policies and Procedures shall be made available to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), GSK shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education.

1. *General Training.* To the extent not already accomplished, within 120 days after the Effective Date, GSK shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain GSK’s:

- a. CIA requirements; and
- b. GSK’s Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* GSK shall provide annual training to each Relevant Covered Person relating to his or her specific job responsibilities. This training shall be known as Specific Training.

By December 31, 2012, each Relevant Covered Person engaged in Promotional Functions, Product Related Functions, or Payer Related Functions shall receive at least three hours of Specific Training in addition to the General Training required above.

For Relevant Covered Persons engaged in Promotional Functions or Product Related Functions, this Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Promotional Functions and to Product Related Functions;
- b. all applicable FDA requirements relating to Promotional Functions and to Product Related Functions;
- c. all GSK Policies and Procedures and other requirements applicable to Promotional Functions and Product Related Functions;
- d. the personal obligation of each individual involved in Promotional Functions and Product Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- f. examples of proper and improper practices related to Promotional Functions and Product Related Functions.

For Relevant Covered Persons engaged in Payer Related Functions, this Specific Training shall include a discussion of topics a-f above, as well as:

- g. all applicable Federal health care program requirements and FDA requirements relating to Payer Related Functions;

- h. GSK's systems and processes applicable to Payer Related Functions;
- i. all GSK Policies and Procedures and other requirements applicable to Promotional Functions and Product Related Functions;
- j. the personal obligation of each individual involved in Payer Related Functions to ensure that all information provided or reported to Payers is complete, accurate and not misleading;
- k. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- l. examples of proper and improper practices relating to Payer Related Functions.

New Relevant Covered Persons shall receive their Specific Training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or by December 31, 2012, whichever is later. A GSK employee who has completed the Specific Training shall oversee a new Relevant Covered Person's work, to the extent that the work relates to any of the Covered Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least three hours of Specific Training in each subsequent Reporting Period.

3. *Compliance Training for Management.* By December 31, 2012, GSK shall provide to managers of employees performing Covered Functions and supervisors of sales personnel (collectively "Management") at least three hours of specialized compliance-related training applicable to the functional area of the manager (Management Compliance Training). This training shall address the responsibility of Management to promote compliance and to identify and mitigate compliance-related risks in their functional areas.

New members of Management shall receive the Management Compliance Training within 30 days after becoming a member of Management or by December 31, 2012, whichever is later.

After receiving the initial Management Compliance Training described in this Section, each Relevant Covered Person shall receive at least three hours of Specialized Compliance Training in each subsequent Reporting Period.

4. *Board Member Training.* Within 150 days after the Effective Date, GSK shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a board member or within 120 days after the Effective Date, whichever is later.

5. *Certification.* Each Covered Person who is required to complete training shall certify, in writing or in electronic form, if applicable, that he or she has received such training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain these certifications, along with all course materials. These shall be made available to OIG, upon request.

6. *Qualifications of Trainer.* Persons responsible for providing the training described above shall be knowledgeable about the subject area of the training, including about applicable Federal health care program and FDA requirements.

7. *Update of Training.* GSK shall review its training annually, and, where appropriate, shall update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during internal audits or the IRO Reviews, the TRACER program (defined below in Section III.D), and any other relevant information.

8. *Computer-based Training.* GSK may provide the training required under this CIA through appropriate computer-based training approaches. If GSK chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training. All applicable requirements to provide a number

of “hours” of training as set forth in this Section III.C may be met with respect to computer-based training by providing the required number of “normative” hours as that term is used in the computer-based training industry.

D. Risk Assessment and Mitigation Process.

GSK represents that prior to the Effective Date, GSK began to implement a standardized process to allow GSK compliance, legal, and business unit leaders to assess and identify risks associated with Government Reimbursed Products that have field force support in the United States (GSK Products). This program is referred to as the Targeted Risk-based Analysis Compliance Evaluations and Review (TRACER) program and is described in more detail in Appendix C. TRACER involves an annual evaluation and mitigation of risks associated with the marketing of the GSK Products. GSK shall maintain a TRACER process for the duration of the CIA.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, GSK shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist GSK in assessing and evaluating its Covered Functions. More specifically, the IRO(s) shall conduct reviews that assess GSK’s systems, processes, policies, procedures, and practices relating to the Covered Functions (including Research and Publication Practices and Authorship-Related Practices) and the TRACER program (collectively “IRO Reviews”).

The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference. Each IRO engaged by GSK shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained including expertise in the pharmaceutical industry with regard to risk identification and mitigation in relation to pharmaceutical product marketing and promotion. Each IRO shall assess, along with GSK,

whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendices B and C, the IRO Reviews shall consist of three components: (1) Systems Reviews and Transactions Reviews relating to the Covered Functions; (2) Additional Items reviews; and (3) Systems Reviews and Transaction Reviews relating to the TRACER program. The Systems Reviews shall assess GSK's systems, processes, policies, and procedures relating to the Covered Functions and the TRACER program.

The IRO Reviews shall cover each of the six calendar years of the CIA. The first IRO Reporting Period shall cover the time from the Effective Date through December 31, 2012. The second through sixth IRO Reporting Periods shall cover, respectively, 2013 and each subsequent calendar year through 2017 (hereafter the "IRO Reporting Periods.") If there are no material changes in GSK's relevant systems, processes, policies, and procedures, the Systems Review shall be performed for the periods covering the second and fifth IRO Reporting Periods. If GSK materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform Systems Reviews for the IRO Reporting Periods in which such changes were made in addition to conducting the Systems Reviews for the second and fifth IRO Reporting Periods, as set forth more fully in Appendices B and C.

The IRO shall perform a limited Transactions Review for the first IRO Reporting Period as set forth more fully in Appendix B. For each of the remaining IRO Reporting Periods, the IRO shall perform full Transaction Reviews as set forth in Appendices B and C. The IRO(s) shall perform all components of each annual Transaction Review.

In addition, the Transactions Reviews for the second through sixth IRO Reporting Periods shall also include a review of up to three

additional areas or practices of GSK identified by the OIG in its discretion (hereafter “Additional Items”). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular IRO Reporting Period, the OIG will consult with GSK and may consider internal audit work conducted by GSK, the Government Reimbursed Product portfolio, the nature and scope of GSK’s promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Appendix B, GSK may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow GSK’s internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

The OIG shall notify GSK of the nature and scope of the IRO review for each of the Additional Items not later than 150 days prior to the end of each applicable IRO Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or GSK shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

*c. Retention of Records.* The IRO and GSK shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and GSK) related to the IRO Reviews.

*2. IRO Review Reports.* The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in each IRO Review Report is described in Appendices B and C.

*3. Validation Review.* In the event OIG has reason to believe that: (a) any of GSK’s IRO Reviews fails to conform to the requirements of this CIA; or (b) the IRO’s findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements

of the CIA and/or the findings or Review results are inaccurate (Validation Review). GSK shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of GSK's final Annual Report shall be initiated no later than one year after GSK's final submission (as described in Section II.B) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify GSK of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, GSK may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. GSK agrees to provide any additional information as may be requested by OIG under this Section III.E.3 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with GSK prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to GSK a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A.

#### F. Disclosure Program.

Prior to the GSK Effective Date, GSK and its Affiliates established a Disclosure Program that includes a mechanism (the toll free "Integrity Helpline") to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with GSK's or a GSK Affiliate's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement (including as they relate to CGMP Activities) believed by the individual to be a potential violation of criminal, civil, or administrative law. The Integrity Helpline may be used by employees of third party suppliers that contract with GSK. GSK and its Affiliates publicize, and shall continue to appropriately publicize, the existence of the Disclosure Program and the Integrity Helpline (e.g., via periodic e-mails to employees, by posting the information in prominent common areas, or through references in the Code of Conduct and during training.)

The Disclosure Program shall emphasize a nonretribution, non-retaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, GSK and/or any applicable Affiliate shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

GSK shall maintain, a disclosure log, which includes a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. This disclosure log shall be made available to OIG upon request.

#### G. Ineligible Persons.

##### 1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

2. *Screening Requirements.* GSK shall ensure that all prospective and current Covered Persons and Manufacturing Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. as part of the hiring or contracting process, GSK shall require all prospective and current Covered Persons and Manufacturing Covered Persons to disclose whether they are Ineligible Persons and shall screen potential Covered Persons and Manufacturing Covered Persons against the Exclusion Lists prior to engaging their services.

b. GSK shall screen all Covered Persons and Manufacturing Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.

c. GSK shall maintain a policy requiring all Covered Persons and Manufacturing Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section III.G affects GSK's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. GSK understands that items or services furnished by excluded persons are not payable by Federal health care programs and that GSK may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether GSK meets the requirements of Section III.G.

3. *Removal Requirement.* If GSK has actual notice that a Covered Person or Manufacturing Covered Person has become an Ineligible Person, GSK shall remove such Covered Person or Manufacturing Covered Person from responsibility for, or involvement with, GSK's business operations related to the Federal health care programs and shall remove such Covered Person or Manufacturing Covered Person from any position for which the Covered Person's or Manufacturing Covered Person's

compensation or the items or services furnished, ordered, or prescribed by the Covered Person or Manufacturing Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person or Manufacturing Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If GSK has actual notice that a Covered Person or Manufacturing Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's or Manufacturing Covered Person's employment or contract term, GSK shall take all appropriate actions to ensure that the responsibilities of that Covered Person or Manufacturing Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

#### H. Employee and Executive Incentive Compensation and Recoupment Policies and Practices.

Pursuant to its existing Patient First program, GSK agrees that it will not provide financial reward (through compensation, including incentive compensation or otherwise) or discipline (through tangible employment action) its prescribing-customer-facing field sales professionals (pharmaceutical sales representatives) or their direct managers based upon the volume of sales of GSK products within a given employee's own territory or the manager's district. The Patient First program includes evaluations for sales representatives based on business acumen, customer engagement, and scientific knowledge about GSK's products. GSK shall continue its Patient First Program, or a substantially equivalent program, during the term of this CIA. GSK commits to maintaining for at least the duration of the CIA, absent agreement otherwise with the OIG, the restrictions on such tangible employment decisions set forth in its Use of Territory/Individual Sales Data policy.

In addition, GSK shall establish and maintain throughout the term of this CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay (*i.e.*, annual bonus, plus long term incentives) for an executive who is discovered to have been involved in any significant misconduct (Executive Financial Recoupment Program). This financial recoupment program shall apply to both covered executives who are either current GSK employees or who are former GSK employees at the time of a Recoupment Determination. The

specific terms and conditions of the Executive Financial Recoupment Program are set forth in Appendix E. GSK commits to maintaining an Executive Financial Recoupment Program consistent with the terms of Appendix E for at least the duration of the CIA absent agreement otherwise by the OIG.

I. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, GSK shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to GSK conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that GSK or a GSK Affiliate has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. GSK shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

J. Reportable Events.

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any FDA requirements relating to the promotion of Government Reimbursed Products (including an FDA Warning Letter issued to GSK);
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by GSK.

A Reportable Event may be the result of an isolated event or a series of occurrences. A Reportable Event that meets the one of the definitions set forth above may arise from within the operations of GSK or any GSK Affiliate.

2. *Reporting of Reportable Events.* If GSK determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, GSK shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Sections III.J.1.a-c.* For Reportable Events under Sections III.J.1.a-c, the report to OIG shall include:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program or FDA authorities implicated;
- b. a description of GSK's actions taken to correct the Reportable Event; and
- c. any further that steps GSK plans to take to address the Reportable Event and prevent it from recurring.

GSK shall not be required to report any Reportable Event which is the subject of an ongoing investigation or legal proceeding by a governmental entity or its agents previously disclosed under Section III.I above.

4. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA authorities implicated.

K. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between GSK and the FDA that materially discusses GSK's or a Covered Person's actual or potential unlawful or improper promotion of GSK's products (including any improper dissemination of information about off-label indications), GSK shall provide a copy of the report, correspondence, or communication to the OIG. GSK shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and

shall provide the OIG with a description of the findings and/or results of the matter, if any.

L. Field Force Monitoring and Review Efforts.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: (1) a Speaker Monitoring Program; (2) direct field observations (Observations) of sales personnel; and (3) the monitoring and review of other records relating to sales personnel's interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.* With regard to speaker programs, GSK shall maintain processes to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements that the speaker may only use GSK approved materials and may not directly or indirectly promote the product for off-label uses.) GSK shall maintain a centralized electronic system through which all speaker programs are administered. This system shall establish controls regarding eligibility and qualifications of speakers and venues for the programs and require that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis conducted by GSK. GSK shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, GSK shall track and review the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs conducted during each Reporting Period. GSK shall require certified evaluations by sales personnel regarding whether a speaker program complied with GSK requirements, and in the event of non-compliance, GSK shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

To the extent not already accomplished, GSK shall institute a Speaker Monitoring Program under which GSK compliance or other appropriately trained GSK personnel who are independent from the functional area being monitored (hereinafter "GSK Monitoring Personnel") shall attend speaker programs during each Reporting Period and

conduct live audits of the programs (Speaker Program Audits). For the first Reporting Period, GSK shall conduct live audits of 150 speaker programs and for the subsequent Reporting Periods, GSK shall conduct live audits of 75 speaker programs. The programs subject to Speaker Program Audits shall be selected both on a risk-based targeting approach and on a sampling approach. For each program reviewed, personnel conducting the Speaker Program Audits shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and GSK representative activities during the program to assess whether the programs were conducted in a manner consistent with GSK's Policies and Procedures. GSK shall maintain the controls around speaker programs as described above, and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations.* As a component of the FFMP, GSK Monitoring Personnel shall conduct observations of field personnel (e.g., sales personnel, MSLs, HOLs, and account managers and directors from the PPV group) to assess whether the messages delivered and materials distributed to HCPs, HCIs, and others are consistent with applicable legal requirements and with GSK's Policies and Procedures. These observations shall be full day ride-alongs with the field personnel (Observations), and each Observation shall consist of directly observing all meetings between field personnel and HCPs during the workday. The Observations shall be scheduled throughout the year, selected by GSK Monitoring Personnel both on a risk-based targeting approach and on a sampling approach, include each therapeutic area and actively promoted product, and be conducted across the United States. At the completion of each Observation, GSK Monitoring Personnel shall prepare a report which includes:

- 1) the identity of the field personnel;
- 2) the identity of the GSK Monitoring Personnel;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with GSK policy; and
- 6) the identification of any potential off-label promotional activity or other improper conduct by the field personnel.

GSK Monitoring Personnel shall conduct at least 50 Observations during the first Reporting Period, and shall conduct at least 25 Observations during the subsequent Reporting Periods.

3. *Records Reviews.* As a component of the FFMP, GSK shall also review various types of records to assess sales personnel interactions with HCPs and HCIs in order to identify potential or actual compliance violations. For each Reporting Period, GSK shall develop and implement a plan for conducting Records Reviews associated with at least three Government Reimbursed Products and a sampling of the personnel supporting those products in regions across the country (as agreed with the OIG for each Reporting Period.) The OIG shall have the discretion to identify the three Government Reimbursed Products to be reviewed for each Reporting Period. The OIG will select the products based on information about GSK's products provided by GSK, upon request by the OIG no later than 60 days prior to the beginning of the Reporting Period, and other information known to the OIG. If the OIG does not identify the Government Reimbursed Products to be reviewed within the first 30 days of the Reporting Period, GSK shall select the three products to be reviewed.

These Records Reviews shall include the monitoring and review of: (1) records and systems relating to sales personnel interactions with HCPs and HCIs (including records from the electronic call reporting system used by sales personnel (which includes call notes), sales communications from managers, sample distribution records, and expense reports); (2) requests for medical information about, or inquiries relating to, Government Reimbursed Products; (3) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of sales personnel interactions with HCPs and HCIs; (4) sales personnel e-mails and other electronic records; and (5) recorded results of the Observations of sales representatives and applicable notes or information from the sales personnel managers.

4. *Reporting and Follow-up.* Personnel conducting the Speaker Program Audits, Observations, and Records Reviews shall have access to all relevant records and information necessary to assess potential or actual compliance violations. Results from the FFMP audits, including the identification of potential violations of policies and/or legal requirements, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate. In the event that a potential violation of GSK's Policies and Procedures or of legal or compliance requirements, including but not limited to potential off-label promotion, is identified during any aspect of the FFMP, GSK shall investigate the incident consistent with established policies and procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.J above, if applicable. Any compliance issues identified during a Speaker Program Audit,

Observation and/or Records Review and any corrective action shall be recorded in the files of the Compliance Officer (or compliance personnel designee).

GSK shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, GSK also shall provide the OIG with copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that GSK took as a result of such determinations. GSK shall make the Observation reports for all other Observations available to the OIG upon request.

M. Monitoring of Non-Promotional Activities.

To the extent not already accomplished, within 120 days after the Effective Date GSK shall develop and implement a monitoring program for the following types of activities: (1) consultant arrangement activities; (2) research-related activities; (3) publication activities; and (4) medical education grants. This program shall be referred to as the Non-Promotional Monitoring Program.

1. *Consultant Arrangement Activities.* To the extent that GSK engages U.S.-based HCPs or HCIs for services that relate to Promotional Functions or to Product Related Functions other than for speaker programs, research-related activities, or publication activities (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs or HCIs shall be referred to herein as Consultants. GSK shall require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by GSK.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a process to develop annual budgeting plans that identify the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the following year. The annual Consultant budgeting plans shall also identify the budgeted amounts to be spent on Consultant-related activities. GSK's Monitoring Personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate purposes in accordance with applicable GSK Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs or HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and type of work product to be generated.) Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by GSK Monitoring Personnel.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, GSK received the work product generated by the Consultant.

Within 120 days after the Effective Date, GSK shall establish a Consultant Monitoring Program through which it shall conduct audits for each Reporting Period (Consultant Program Audits) of at least 50 Consultant arrangements with HCPs for the first Reporting Period and 25 Consultant arrangements for subsequent Reporting Periods. The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a sampling approach. GSK Monitoring Personnel conducting the Consultant Program Audits shall review needs assessment documents, consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with GSK's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

2. *Research-Related Activities.* To the extent that GSK engages or supports U.S.-based HCPs or HCIs to conduct Research (as defined above in Section III.B.3.u), such HCPs and HCIs shall be referred to collectively as "Researchers". GSK shall require all Researchers to enter written agreements describing the scope of the clinical research or other work to be performed, the fees to be paid or support to be given, and compliance obligations for the Researchers. Researchers retained to conduct Research shall be paid

according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by GSK.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish an annual budgeting plan for Researchers that identifies the business or scientific need or scientific opportunity for, and the estimated numbers of, the various Researcher engagements and activities to occur during the year. The annual Researcher budgeting plan shall also identify the budgeted amounts to be spent on Researcher-related activities during the year. GSK Monitoring Personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Research arrangements and related events are used for legitimate purposes in accordance with GSK Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a process to ensure that a needs assessment has been completed to justify the retention of the Researcher prior to the retention of the Researcher. The needs assessment shall identify the business or scientific need for the information to be provided by the Researcher and provide specific details about the research arrangement (including, for example, information about the numbers and qualifications of the HCPs or HCIs to be engaged, a description of the proposed research to be done (including the research protocol) and type of work product to be generated). Any deviations from the Researcher budgeting plans shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by GSK Monitoring Personnel.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall amend its policies and procedures in a manner designed to ensure that each Researcher performed the work for which the Researcher was engaged.

Within 120 days after the Effective Date, GSK shall establish a Researcher Monitoring Program through which it shall conduct audits for each Reporting Period (Researcher Program Audits). GSK shall review 20 Researcher arrangements with HCPs or HCIs for the first Reporting Period and 10 Researcher Arrangements for subsequent Reporting Periods. The Researcher Monitoring Program shall review Researcher arrangements both on a risk-based targeting approach and on a sampling approach. GSK Monitoring Personnel conducting the Researcher Program Audits shall review needs assessment documents, proposal and/or protocol documents, approval documents, contracts, and payments in order to assess whether the programs and arrangements were

supported by GSK and performed by the Researchers in a manner consistent with GSK's Policies and Procedures. Results from the Researcher Program Audits, including identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

3. *Publication Activities.* GSK represents that it generally does not engage HCPs or HCIs exclusively to produce articles or other publications relating to GSK-Sponsored Research, and that generally HCPs or HCIs who perform this work do so as part of an engagement for Research Related Activities. To the extent that, in connection with Research Related Activities, U.S.-based HCPs or HCIs produce articles or other publications relating to GSK-Sponsored Research (collectively "Publication Activities") such HCPs or HCIs shall be referred to as Authors. GSK shall require all Authors to enter written agreements describing the terms of the arrangement between GSK and the Author and compliance obligations of the Authors. Authors shall be paid according to the centrally managed, pre-set rate structure that is established for Research Related Activities but will not be paid separately for authorship or other publication-specific activity (provided that GSK may reimburse travel expenses incurred to make public presentations of data from GSK-Sponsored Research Studies). If, in a departure from usual practice, GSK engages an HCP or HCI for a stand-alone project involving the production of an article or other publication relating to GSK-Sponsored Research (*e.g.*, a review article summarizing research in a field that includes GSK-Sponsored Research), GSK will require a written agreement with the same compliance obligations as it requires of Author generally and will pay for the work according to the centrally managed, pre-set rate structure as applied to Consultants generally.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a process to develop annual plans that identify the business needs for and the estimated numbers of various Publication Activities (Publications Plans). The annual Publications Plan shall also identify the budgeted amounts to be spent on Publication Activities. GSK's U.S. compliance personnel shall be involved in the review and approval of such annual Publications Plans, including any modification of an approved plan. The purpose of this review shall be to ensure that Publication Activities and related events are used for legitimate purposes in accordance with GSK Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a needs assessment process for Publication Activities. This process

shall ensure that a needs assessment has been completed prior to the retention of an Author for a Publication Activity. The needs assessment shall provide specific details about Publication Activities to be performed (including a description of the proposed work to be done, type of work product to be generated, and the purpose for the work.) Any deviations from the Publications Plan shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by GSK Monitoring Personnel.

Within 120 days after the Effective Date, GSK shall establish a Publication Monitoring Program through which it shall conduct audits for each Reporting Period of at least 50 Publication Activities for the first Reporting Period and 25 Publication Activities for subsequent Reporting Periods. The Publication Monitoring Program shall select publications for review both on a risk-based targeting approach and on a sampling approach. GSK Monitoring Personnel conducting the Publication Monitoring Program shall review needs assessment documents, proposal documents, approval documents, contracts, payments and materials relating to the Publication Activities (including work product resulting from the Activities), in order to assess whether the activities were conducted in a manner consistent with GSK's Policies and Procedures. Results from the Publication Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

4. *Medical Education Grant Activities.* GSK represents that it provides grants for medical education of HCPs on a limited basis and that it provides such grants only to educational providers (including academic medical centers, hospital or delivery systems, or professional medical associations that represent HCPs who deliver patient care) that satisfy pre-set criteria established by GSK. Potentially eligible educational providers are selected annually and invited to submit grant proposals for a future fiscal year. GSK represents that it does not provide funding to any commercial providers of medical education.

GSK's Medical Affairs organization reviews the grant proposals from the potential providers and makes recommendations for approval based on objective criteria, compliance policies and procedures, and budget availability. GSK represents that its commercial organization (including the sales and marketing departments) has no involvement in, or influence over, the review and approval of medical education grants. GSK shall continue the medical education grant process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at

least 60 days prior to the implementation of any new system subsequent to the Effective Date.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 10 medical education grants for the first Reporting Period and 5 medical education grants for subsequent Reporting Periods. The Grants Monitoring Program shall select grants for review both on a risk-based targeting approach and on a sampling approach. GSK Monitoring Personnel conducting the Grants Monitoring Program shall review proposal documents (including grant requests), approval documents, contracts, payments and materials relating to the grant office's review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with GSK's Policies and Procedures. Results from the Grant Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

*5. Follow Up Reviews and Reporting.* In the event that a potential violation of GSK's Policies and Procedures or of legal or compliance requirements, including but not limited to potential improper promotion, are identified during any aspect of the Non-Promotional Monitoring Program, GSK shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.J above, if applicable. Any compliance issues identified during any Non-Promotional Monitoring Program referenced above, and any corrective action, shall be recorded in the files of the U.S. Compliance Department.

GSK shall include a summary of the Non-Promotional Monitoring Program and the results of the Non-Promotional Monitoring Program as part of each Annual Report. As part of each Annual Report, GSK also shall provide the OIG with descriptions of any instances identified through the Non-Promotional Monitoring Program in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated GSK's requirements or Policies and Procedures, and a description of the action(s) that GSK took as a result of such determinations. GSK shall make the documents relating to the Non-Promotional Monitoring Program available to the OIG upon request.

N. Notices to Health Care Providers, Entities, Payers. Within 90 days after the Effective Date, GSK shall send, by first class mail, postage prepaid with delivery confirmation, a notice containing the language set forth below to all HCPs and HCIs that GSK currently details. This notice shall be dated and shall be signed by GSK's President. The body of the letter shall state the following:

As you may be aware, GSK recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with the promotion and use of some of its products. This letter provides you with additional information about the settlement, explains GSK's commitments going forward, and provides you with access to information about those commitments.

In general terms, the Government alleged that GSK unlawfully promoted Wellbutrin, Paxil, Advair, Lamictal, and Zofran for uses not approved by the Food & Drug Administration (FDA) and that GSK engaged in other improper conduct relating to several of its other drugs including Avandia. To resolve these matters, GSK pled guilty to three misdemeanor criminal violations of the Federal Food, Drug & Cosmetic Act and agreed to pay a criminal fine of \$1 billion. In addition, the Government alleged that GSK violated the False Claims Act and GSK entered into three civil settlements to resolve these allegations pursuant to which GSK agreed to pay \$ 2 billion to the Federal Government and State Medicaid programs. More information about this settlement may be found at the following: **[GSK shall include a link to the USAO, OCL, and GSK websites in the letter.]**

As part of the federal settlement, GSK also entered into a five-year corporate integrity agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. The CIA is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, GSK agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by GSK's representatives to GSK's Compliance Department or the FDA.

GSK is fully committed to meeting the terms of the CIA and to sales and

marketing practices that promote compliance. We have fundamentally changed our procedures for compliance, marketing and selling in the United States. For example, we now compensate our medical sales representatives based on the quality of service they deliver to customers, not on sales targets.

Please call GSK at **XXXX** or **visit us at [insert name of web link]** if you have questions about the settlement referenced above or to report any instances in which you believe that a GSK representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by a GSK representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about the products to **XXXXX**.

Within 90 days after the Effective Date, GSK shall send to all Payers with whom GSK currently has contracts or enters into contracts for formulary access or rebates (including all state Medicaid programs), by first class mail, postage prepaid with delivery confirmation, a notice containing the language set forth. This notice shall be dated and shall be signed by GSK's President. The body of the letter shall state the following:

As you may be aware, GSK recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with the promotion and of some of its products. This letter provides you with additional information about the settlement, explains GSK's commitments going forward, and provides you with access to information about those commitments.

In general terms, the Government alleged that GSK unlawfully promoted Wellbutrin, Paxil, Advair, Lamictal, and Zofran for uses not approved by the Food & Drug Administration (FDA) and that GSK engaged in other improper conduct relating to several of its other drugs including Avandia. To resolve these matters, GSK pled guilty to three misdemeanor criminal violations of the Federal Food, Drug & Cosmetic Act (FDCA) and agreed to pay a criminal fine of \$ 1 billion. In addition, the Government alleged that GSK violated the False Claims Act and GSK entered into three civil settlements to resolve these allegations pursuant to which GSK agreed to pay \$ 2 billion to the Federal Government and State Medicaid programs.

GlaxoSmithKline LLC  
Corporate Integrity Agreement

More information about this settlement may be found at the following:  
**[GSK shall include a link to the USAO, OCL, and GSK websites in the letter.]**

As part of the federal settlement, GSK also entered into a five-year corporate integrity agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. The CIA is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, GSK agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify payers about the settlement and inform them that they can report any questionable practices by GSK's representatives to GSK's Compliance Department or the FDA.

GSK is fully committed to meeting the terms of the CIA and to sales and marketing practices that promote compliance. We have fundamentally changed our procedures for compliance, marketing and selling in the United States. For example, we now compensate our medical sales representatives based on the quality of service they deliver to customers, not on sales targets.

In addition, GSK is committed to promoting its products in a manner consistent with the FDA approved label for the product. GSK will pay rebates under applicable agreements (Rebates) involving a prior authorization or formulary requirement (a "Restriction") in relation to the drugs at issue in this settlement, and will not reduce or alter its Rebates due to such a Restriction, provided that the Restriction: (1) does not limit any patient from receiving such drugs, including at the point of sale, for uses that are consistent with the FDA-approved label for each product; (2) is applied consistently across the therapeutic class; (3) is consistent with GSK's policies, procedures and financial guidelines; and, (4) does not require the use of another manufacturer's drug for a use that is not consistent with the FDA approved label for the other product. This paragraph shall not be interpreted to require GSK to contract or not to contract with any Payer. GSK shall administer its agreements with Payers in a manner consistent with the requirements of this paragraph, including agreeing to amend or modify applicable agreements to be consistent with this provision.

Please call GSK at **XXXX** or **visit us at [insert name of web link]** if you have questions about the settlement referenced above or to report any instances in which you believe that a GSK representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by a GSK representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about the products to **XXXXX**.

The Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notices. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The log of all calls and messages received in response to the notices shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, GSK shall provide to the OIG a summary of the calls and messages received.

**O. Reporting of Physician Payments.**

Prior to the Effective Date, GSK began a voluntary Physician Payment Transparency Program through which GSK posted on its corporate website quarterly reports of payments to physicians for speaking and consulting fees. GSK shall continue to post such reports until the Annual Reporting requirements of Section III.O.1 take effect.

**1. *Reporting of Payment Information.***

**Quarterly Reporting:** On or before March 1, 2013, GSK shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities who or which received Payments (as defined in Section III.O.2) directly or indirectly from GSK during the fourth quarter of 2012 and the aggregate value of such Payments. Thereafter, 60 days after the end of each calendar quarter, GSK shall post on its website a report of the cumulative value of the Payments provided to each physician and Related Entity during the preceding calendar quarter.

**Annual Reporting:** On or before March 1, 2013, and 60 days after the end of each subsequent calendar year, GSK shall post on its website a report of the cumulative value

of the Payments provided to all U.S.-based physicians and Related Entities directly or indirectly from GSK during the prior applicable calendar year. Each quarterly and annual report shall be easily accessible and readily searchable.

Each listing made pursuant to this Section III.O shall include a complete list of all individual physicians or Related Entities to whom or which GSK made Payments in the preceding quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or name of Related Entity. The Payment amounts in the lists shall be reported in the actual amount paid for all physicians or Related Entity on the listing. For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city and state that the physician has provided to GSK for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

## 2. *Definitions and Miscellaneous Provisions.*

(i) GSK shall continue to make each annual listing and the most recent quarterly listing of Payments available on its website during the term of the CIA. GSK shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual and/or quarterly listings of Payments. Nothing in this Section III.O affects the responsibility of GSK to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entity.

(ii) For purposes of Section III.O.1, "Payments" is defined to include all "payments or other transfers of value" as that term is defined in §1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder. The term Payments includes, by way of example, the types of payments or transfers of value enumerated in §1128G(a)(1)(A)(vi) of the Affordable Care Act. The term includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom GSK would otherwise report a Payment if made directly to the physician. The term Payments also includes any payments or transfers of value made, directly by GSK or by a vendor retained by GSK to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

(iii) For purposes of its annual and quarterly website postings as described above, and only with regard to payments made pursuant to product research or development agreements and clinical investigations as set forth in § 1128G(c)(E) of the Affordable Care Act, GSK may delay the inclusion of such payments on its website listings consistent with § 1128G(c)(E) of the Act and any subsequent regulations promulgated thereunder.

(iv) The term “Payments” does not include transfers of value or other items that are not included in or are excluded from the definition of “payment” as set forth in § 1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder.

(v) For purposes of this Section III.O, the term “Related Entity” is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

P. Other Transparency/Disclosure Initiatives.

GSK represents that it posts on its company website the following information with respect to both grants and charitable contributions in the United States: GSK shall continue to post (and provide updates to) the above-described information about grants and charitable contributions throughout the term of this CIA. GSK shall notify the OIG in writing at least 60 days prior to any change in the substance of its policies regarding the funding of grants and charitable contributions or posting of the above-referenced information relating to such funding.

GSK shall require all Consultants to comply fully with all applicable disclosure obligations relating to their relationship with GSK that may be externally imposed on the Consultants based on their affiliation with formulary or P&T committees or committees associated with the development of treatment protocols or standards. GSK shall maintain this requirement throughout the term of this CIA. GSK represents that within 120 days after the Effective Date, GSK shall, if necessary, amend its policies relating to Consultants to explicitly state that GSK requires all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with GSK that may be externally imposed on the Consultants based on their affiliation with formulary, P&T committees, or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any

amendment to its contracts with Consultants and in any new contracts with Consultants entered into after 150 days following the Effective Date, GSK shall include an explicit requirement that the Consultants fully comply with all applicable disclosure requirements, as referenced above in this paragraph. GSK shall continue these disclosure requirements throughout the term of this CIA.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall post or make available information on its company website about FDA postmarketing commitments (PMCs). The GSK website or links included therein shall provide access to general information about the PMC process, descriptions of ongoing GSK studies, and information about the nature and status of the post-marketing commitments. GSK shall continue to post or make available the above-described information about PMCs on its website or links included therein throughout the term of this CIA.

#### **IV. CHANGES TO BUSINESS UNITS OR LOCATIONS**

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, GSK changes locations or closes a business unit or location related to or engaged in any of the Covered Functions or in CGMP Activities, GSK shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, GSK purchases or establishes a new business unit or location related to or engaged in any of the Covered Functions or in cGMP Activities, GSK shall notify OIG no later than five days after the date that the purchase or establishment of the new business unit or location is publicly disclosed by GSK. This notification shall include the address of the new business unit or location, phone number, fax number, the location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which GSK currently submits claims (if applicable). Each new business unit or location and all Covered Persons or Manufacturing Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, GSK proposes to sell any or all of its business units or locations that are subject to this CIA (including the terms of Appendix D), GSK shall notify OIG of the proposed sale at no

later than five days after the sale is publicly disclosed by GSK. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

## **V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Implementation Report. Within 150 days after the Effective Date, GSK shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the members of the Board of Directors referenced in Section III.A.3;
4. the names of the DCOs required by Section III.A.4;
5. the names and positions of the Certifying Employees required by Section III.A.6;
6. a copy of GSK's Code of Conduct required by Section III.B.1;
7. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
8. (a) a copy of the letter (including all attachments) required by Section II.C.9 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements between GSK and the party

employing Third Party Personnel; and (c) a description of each entity's response to GSK's letter;

9. a summary of all Policies and Procedures required by Section III.B.3 (a copy of such Policies and Procedures shall be made available to OIG upon request);

10. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to participate in General Training and Board Member Training, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.<sup>2</sup>

11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A; (d) a summary and description of any and all current and prior engagements and agreements between GSK and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to GSK;

12. a description of the Disclosure Program required by Section III.F;

13. a description of the process by which GSK fulfills the requirements of Section III.G regarding Ineligible Persons;

14. a certification by the Compliance Officer that the notices required by Section III.N was mailed to each HCP, HCI, and Payer, the number of HCPs, HCIs and

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<sup>2</sup> In Addition to the Implementation Report, GSK shall submit to OIG by January 30, 2013 a letter containing the information specified in Section V.A.10 as it pertains to Specific Training and Management Training as required by Section III.C.

Payers to whom or which the notice was mailed, a sample copy of the notices required by Section III.N, and a summary of the calls or messages received in response to the notices;

15. a certification from the Compliance Officer that, if required under Section III.O and to the best of his/her knowledge, information regarding Payments has been posted on GSK's website as required by Section III.O;

16. a list of all of GSK's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of any each Federal health care program contractor to which GSK currently submits claims (if applicable);

17. a description of GSK's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

18. the certifications required by Section V.D.

B. Annual Reports. GSK shall submit to OIG annually a report with respect to the status of, and findings regarding, GSK's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee, the Board of Directors, the DCOs or the group of Certifying Employees described in Sections III.A.2-4 and 6;

2. a copy of the resolution by the Board required by Section III.A.3;

3. the number of individuals required to review GSK's Code of Conduct and complete the certifications required by Section III.B.1, the percentage of individuals who have completed such certifications, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

4. (a) a copy of the letter (including all attachments) required by Section II.C.9 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements between GSK and the party employing Third Party Personnel; and (c) a description of each entity's response to GSK's letter;

5. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B, including any changes to the Research and Publication Practices and Authorship-Related Practices, and the reasons for such changes (e.g., change in applicable requirements);

6. the following information regarding each type of training required by Section III.C:

a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to complete each type of training specified in Section III.C, percentage of individuals who completed the training, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

7. a summary of any significant changes to the TRACER program required by Section III.D;

8. a complete copy of all reports prepared pursuant to Section III.E, and Appendices B-C along with a copy of the IRO's engagement letters;

9. GSK's response to the reports prepared pursuant to the reviews outlined in Section III.E and Appendices B-C, along with corrective action plan(s) related to any issues raised by the reports;

10. a summary and description of any and all current and prior engagements and agreements between GSK and the IRO (if different from what was submitted as part of the Implementation Report);

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11. certifications from the IRO regarding its professional independence and objectivity with respect to GSK;

12. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements (including CGMP Activities), or Government Reimbursed Products;

13. any changes to the process by which GSK fulfills the requirements of Section III.G regarding Ineligible Persons;

14. a summary of any changes to GSK's employee and executive incentive compensation and recoupment programs required by Section III.H and Appendix E and the information regarding Triggering Events and Recoupment Determinations required to be reported pursuant to Section E of Appendix E;

15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

16. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

17. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.K. This summary shall include a description of the matter and the status of the matter;

18. a summary of the FFMP and the results of the FFMP required by Section III.L, including copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that GSK took as a result of such determinations;

19. a summary of the Non-Promotional Monitoring Program and the results of the program described in Section III.M, including detailed description of any identified instances in which it was determined that the activities violated GSK's policies or that improper promotion of Government Reimbursed Products occurred and a description of

the action(s) GSK took as a result of such determinations;

20. a summary of the calls and messages received in response to the notices required by Section III.N and the disposition of those calls and messages;

21. a certification from the Compliance Officer that information regarding Payments has been posted on GSK's website as required by Section III.O;

22. a description of all changes to the most recently provided list of GSK's locations (including addresses) as required by Section V.A.16; the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers;

23. a description of any additional, updated, supplemental or changed information submitted to any Compendia in accordance with Section III.B.3.t; and a description of all arrangements, processing fees, and other payments or financial support (if any) with or made to any Compendia evaluated during the annual review described in Section III.B.3.t; and

24. the certifications required by Section V.D.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. IRO Initial Report. By March 1, 2013, GSK shall submit to OIG a report with respect to the status of, and findings regarding, the IRO Reviews for the first IRO Reporting Period (IRO Initial Report).

The IRO Initial Report shall include at a minimum:

1. a complete copy of all reports prepared pursuant to Section III.E, and Appendix B along with a copy of the IRO's engagement letters;

2. GSK's response to the reports prepared pursuant to the reviews outlined in Section III.E and Appendix B, along with corrective action plan(s) related to any issues raised by the reports;

3. a summary and description of any and all current and prior engagements and agreements between GSK and the IRO (if different from what was submitted as part of the Implementation Report);

4. certifications from the IRO regarding its professional independence and objectivity with respect to GSK;

D. Certifications.

1. Certifying Employees: In each Annual Report, GSK shall include the certifications of Certifying Employees as required by Section III.A.6;

2. Compliance Officer: In the Implementation Report, and each Annual Report, GSK shall include the following individual certification by the Compliance Officer:

a. to the best of his or her knowledge, except as otherwise described in the report, GSK is in compliance with the requirements of this CIA;

b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;

c. to the best of his or her knowledge, GSK has complied with its obligations under the Settlement Agreement: (1) not to resubmit to any Federal health care program Payers any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (2) not to charge to or otherwise seek payment from federal or state Payers for unallowable costs (as defined in the Settlement Agreement); and (3) to identify and adjust any past charges or claims for unallowable costs;

d. GSK's: (1) Policies and Procedures as referenced in Section III.B.3 above; (2) templates for standardized contracts and other similar documents; and (3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, GSK's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside GSK have been reviewed

by competent regulatory, medical, or, as appropriate, legal counsel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by GSK and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request;

e. GSK's Target Plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.j) and, for each product the Target Plans were found to be consistent with GSK's policy objectives as referenced above in Section III.B.3.j; and

f. GSK has maintained an employee and executive incentive compensation and recoupment program in accordance with the terms set forth above in Section III.H and Appendix E.

3. Certification for the IRO Initial Report: In the IRO Initial Report, GSK shall include an individual certification by the Compliance Officer that he or she has reviewed the report and has made reasonable inquiry regarding its content and believes the information in the report is accurate and truthful.

E. Designation of Information. GSK shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. GSK shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG: Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

GSK: Michael L. Shaw  
Vice President & Compliance Officer  
North America Pharmaceuticals  
GlaxoSmithKline  
Three Franklin Plaza  
200 N. 16<sup>th</sup> Street  
Philadelphia, PA 19102  
Telephone: 215.751.7337  
Facsimile: 215.751.7547

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, GSK may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

## **VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of GSK's or an applicable GSK Affiliate's books, records, and other documents and supporting

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materials and/or conduct on-site reviews of any of GSK's locations for the purpose of verifying and evaluating: (a) GSK's or an applicable GSK Affiliate's compliance with the terms of this CIA (including Appendix D); and (b) GSK's or an applicable GSK Affiliate's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements (including CGMP Activities). The documentation described above shall be made available by GSK or the applicable GSK Affiliate to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of GSK's or the applicable GSK Affiliate's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. GSK or the applicable GSK Affiliate shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. GSK's or the applicable GSK Affiliate's employees may elect to be interviewed with or without a representative of GSK or the applicable GSK Affiliate present.

#### **VIII. DOCUMENT AND RECORD RETENTION**

GSK and its Affiliates shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA (including Appendix D) until the end of 2018 (or longer if otherwise required by law) from the Effective Date.

#### **IX. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify GSK prior to any release by OIG of information submitted by GSK pursuant to its obligations under this CIA and identified upon submission by GSK as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, GSK shall have the rights set forth at 45 C.F.R. § 5.65(d).

#### **X. BREACH AND DEFAULT PROVISIONS**

GSK is expected to fully and timely comply with all of the CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, GSK and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day GSK fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board compliance obligations, including the resolution from the Board;
- d. the management accountability and certification obligations;
- e. a written Code of Conduct;
- f. written Policies and Procedures;
- g. the training of Covered Persons, Relevant Covered Persons, Management, and Board Members;
- h. a TRACER program;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;
- k. an employee and executive incentive compensation and recoupment program as required by Section III.H and Appendix E;
- l. notification of Government investigations or legal proceedings as required by Section III.I;

- m. reporting of Reportable Events as required in Section III.J;
- n. notification of written communications with FDA as required by Section III.K;
- o. a program for FFMP as required by Section III.L;
- p. a program for Non-Promotional Monitoring Program as required by Section III.M;
- q. notifications to HCPs, HCIs, and Payers as required by Section III.N; and
- r. posting of any Payments as required by Section III.O.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day GSK fails to engage and use an IRO as required in Section III.E and Appendices A-C.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day GSK fails to submit the Implementation Report or any Annual Report to OIG in accordance with the requirements of Section V of the CIA or of Appendix D by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day GSK fails to submit any IRO Review report (including the IRO Initial Report) in accordance with the requirements of Sections III.E and III.V and Appendices A-C.

5. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day GSK fails to establish and implement any of the following obligations as described in Section III of Appendix D:

- a. a GMS Compliance Officer;
- b. a GMS Compliance Committee;
- c. the Board compliance obligations, including the resolution from

the Board;

- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Manufacturing Covered Persons;
- g. cGMP Requirements;
- h. reporting of Manufacturing Reportable Events; or
- i. reporting of a recall under Section III.F of Appendix D.

6. A Stipulated Penalty of \$1,500 for each day GSK or a GSK Affiliate fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date GSK or a GSK Affiliate fails to grant access.)

7. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of GSK as part of its Implementation Report, the IRO Initial Report, or any Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

8. A Stipulated Penalty of \$10,000 for each day that GSK fails to timely submit any report required under Section III.D.3.a or III.D.3.b of Appendix D.

9. A Stipulated Penalty of \$10,000 for each lot of each Covered Product for each day that GSK fails to initiate a recall for specified lots under Section III.D of Appendix D after receipt of a Final Determination.

10. A Stipulated Penalty of \$10,000 for each lot of each Covered Product for each day that GSK fails to complete a recall within a deadline established in the Final Determination for specified lots under Section III.D of Appendix D.

11. A Stipulated Penalty of \$1,000 for each day GSK or a GSK Affiliate fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to GSK or a GSK Affiliate stating the specific grounds for its determination that GSK or a GSK Affiliate has failed to comply fully and adequately with the CIA

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obligation(s) at issue and steps GSK or a GSK Affiliate shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after GSK or a GSK Affiliate receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 10 of this Section.

B. Timely Written Requests for Extensions. GSK may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after GSK fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after GSK receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that GSK has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify GSK of: (a) GSK's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, GSK shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event GSK elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until GSK cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that GSK has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by GSK to report a Reportable Event and take corrective action as required in Section III.J of the CIA or Section III.E of Appendix D;
- c. a failure to engage and use an IRO in accordance with Section III.E and Appendices A-C;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;
- e. a failure of the Board to issue a resolution in accordance with Section III.A.3 of the CIA or Section III.A.3 of Appendix D.
- f. a failure by GSK to timely initiate a recall of Covered Products sold in the United States pursuant to a Final Determination made under Section III.D of Appendix D after receipt of a Final Determination; or
- g. a failure by GSK to timely complete a recall of Covered Products sold in the United States as required in the Final Determination after receipt of the Final Determination under Appendix D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by GSK constitutes an independent basis for GSK's exclusion from participation in the Federal health care programs. Upon a determination by OIG that GSK has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify GSK of: (a) GSK's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* GSK shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. GSK is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30 day period, but that: (i) GSK has begun to take action to cure the material breach; (ii) GSK is pursuing such action with due diligence; and (iii) GSK has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, GSK fails to satisfy the requirements of Section X.D.3, OIG may exclude GSK from participation in the Federal health care programs. OIG shall notify GSK in writing of its determination to exclude GSK (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of GSK's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, GSK may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

### E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to GSK of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, GSK shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether GSK was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. GSK shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders GSK to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless GSK requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether GSK was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) GSK had begun to take action to cure the material breach within that period; (ii) GSK has pursued and is pursuing such action with due diligence; and (iii) GSK provided to OIG within that period a reasonable timetable for curing the material breach and GSK has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for GSK, only after a DAB decision in favor of OIG. GSK's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude GSK upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that GSK may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. GSK shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of GSK, GSK shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

GSK and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of GSK;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;

D. The undersigned GSK signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

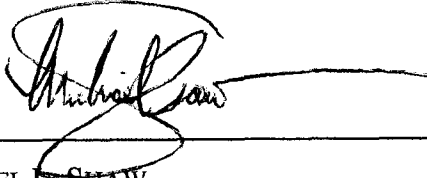
ON BEHALF OF GLAXOSMITHKLINE LLC



DEIRDRE CONNELLY  
President  
GlaxoSmithKline LLC

6-28-2012

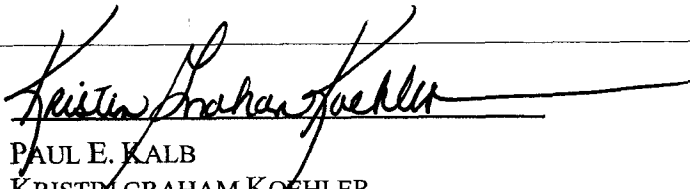
DATE



MICHAEL L. SHAW  
Vice President & Compliance Officer  
North America Pharmaceuticals  
GlaxoSmithKline LLC

6/28/2012

DATE



PAUL E. KALB  
KRISTIN GRAHAM KOEHLER  
LAUREN K. ROTH  
Sidley Austin LLP  
Counsel for GlaxoSmithKline LLC

6/28/2012

DATE

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**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



GREGORY E. DEMSKE  
Chief Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services

6/22/12  
DATE



MARY E. RIORDAN  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

4/28/12  
DATE

CHRISTINA K. MCGARVEY  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

DATE

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ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

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GREGORY E. DEMSKE  
Chief Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services

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DATE

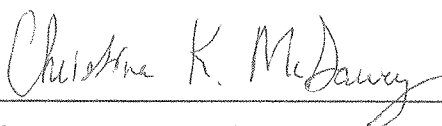
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MARY E. RIORDAN  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services


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DATE

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CHRISTINA K. MCGARVEY  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

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DATE

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## **Appendix A to CIA for GlaxoSmithKline LLC**

### **Independent Review Organization**

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

#### **A. IRO Engagement.**

GSK shall engage an IRO (or IRO(s)) that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.11 of the CIA or any additional information submitted by GSK in response to a request by OIG, whichever is later, OIG will notify GSK if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, GSK may continue to engage the IRO.

If GSK engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, GSK shall submit the information identified in Section V.A.11 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by GSK at the request of OIG, whichever is later, OIG will notify GSK if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, GSK may continue to engage the IRO.

#### **B. IRO Qualifications.**

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and have expertise in applicable Federal health care program and FDA requirements that relate to the Covered IRO Functions, including expertise relating to: i) marketing and promotional activities associated with pharmaceutical products; ii) research regarding such products; and iii) publication, authorship, and disclosure activities associated with such research). The assigned individuals shall also be experienced in risk identification and mitigation in relation to pharmaceutical product marketing and promotion. The assigned individuals also shall be knowledgeable about the general requirements of the Federal health care programs under which GSK products are reimbursed;

2. assign individuals to design and select the samples for the IRO Transactions Reviews who are knowledgeable about appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each component of each IRO Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;

3. if in doubt of the application of a particular Federal health care program or FDA requirement, request clarification from the appropriate authority (e.g., CMS or FDA);

4. respond to all OIG inquiries in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendices B and C to the CIA.

D. Independence and Objectivity.

The IRO must perform the IRO Reviews in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination.

1. *GSK Termination of IRO.* If GSK terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, GSK must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. GSK must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of the termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as

described in Paragraph C, OIG may, at its sole discretion, require GSK to engage a new IRO in accordance with Paragraph A of this Appendix. GSK must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring GSK to engage a new IRO, OIG shall notify GSK of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, GSK may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with GSK prior to requiring GSK to terminate the IRO. However, the final determination as to whether or not to require GSK to engage a new IRO shall be made at the sole discretion of OIG.

## **Appendix B to CIA for GlaxoSmithKline LLC**

### **Independent Review Organization Reviews**

#### **I. Covered Functions Review, General Description**

As specified more fully below, GlaxoSmithKline (GSK) shall retain an Independent Review Organization (IRO) (or IROs) to perform reviews (IRO Reviews) to assist GSK in assessing and evaluating its systems, processes, policies, procedures, and practices related to certain of GSK's Covered Functions (collectively, "IRO Covered Functions"). The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. GSK may engage, at its discretion, a single IRO to perform both components of the IRO Review provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in GSK's systems, processes, policies, and procedures relating to the Covered IRO Functions, the IRO shall perform the Systems Review for the second and fifth IRO Reporting Periods. If GSK materially changes its systems, processes, policies, and procedures relating to the Covered IRO Functions, the IRO shall perform a Systems Review for the IRO Reporting Period(s) in which such changes were made in addition to conducting the Review for the second and fifth IRO Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each IRO Reporting Period of the CIA.

#### **II. IRO Systems Review**

##### **A. Description of Reviewed Policies and Procedures**

The Covered IRO Functions Systems Review shall be a review of GSK's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain of the Covered Functions. Where practical, GSK personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by GSK in accordance with the preceding sentence.

Specifically, the IRO shall review GSK's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

- 1) GSK's systems, processes, policies, and procedures applicable to the manner in which GSK field personnel (including sales personnel, marketing personnel, MSLs, HOLs, and personnel from the PPV group) and personnel from the Medical Affairs department (including MISs) handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved (*i.e.*, off-label) uses of Government Reimbursed Products) and the dissemination of materials relating to the uses of these products. This review shall include:
  - a) the manner in which GSK sales personnel and PPV personnel handle requests for information about off-label uses of Government Reimbursed Products (*i.e.*, by referring all such requests to Medical Affairs personnel at GSK);
  - b) the manner in which Medical Affairs personnel, including those at GSK's headquarters, handle and respond to requests for information about off-label uses of Government Reimbursed Products (including tracking the requests and using pre-approved materials for purposes of responding to the request);
  - c) the form and content of information and materials related to Government Reimbursed Products disseminated to physicians, pharmacists, or other health care professionals (collectively "HCPs"), and health care institutions (HCIs), Payers, and formulary decision-makers by GSK;
  - d) GSK's systems, processes, policies, and procedures (including the Inquiries Database) to track requests to Medical Affairs for information about off-label uses of products and responses to those requests;
  - e) the manner in which GSK collects and supports information reported in any systems used to track and respond to requests to Medical Affairs for Government Reimbursed Product information, including its Inquiries Database;

- f) the processes and procedures by which Medical Affairs, the Compliance Officer, or other appropriate individuals within GSK identify situations in which it appears that off-label or other improper promotion may have occurred; and
  - g) GSK's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;
- 2) GSK's systems, processes, policies, and procedures applicable to the manner and circumstances under which its Medical Affairs personnel (including MSLs, HOLs, or analogous personnel) participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) regarding Government Reimbursed Products and the role of the Medical Affairs personnel at such meetings or events;
- 3) GSK's systems, processes, policies, and procedures relating to GSK's internal review of promotional materials related to Government Reimbursed Products disseminated to HCPs, HCIs and Payers and individuals or entities (*e.g.*, PBMs) acting on behalf of HCPs, HCIs or government payers;
- 4) GSK's systems, policies, processes and procedures (the "Patient First Program") relating to incentive compensation for Relevant Covered Persons who are prescriber-facing sales personnel and their direct managers, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Government Reimbursed Products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that GSK establishes different methods of compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;
- 5) GSK's systems, policies, processes and procedures relating to the Executive Financial Recoupment Program described in Section III.H of the CIA and in Appendix E;

- 6) GSK's systems, processes, policies, and procedures relating to the development and review of Target Plans (as defined in Section III.B.3.j of the CIA) for Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the Target Plans based on expected utilization of Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;
- 7) GSK's systems, processes, policies, and procedures relating to Sample Distribution Policies and Procedures (as defined in Section III.B.3.k of the CIA). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from GSK (including, separately, from GSK sales representatives and other GSK personnel or components). It shall also include a review of whether samples of Government Reimbursed Products are distributed by GSK through sales representatives or are distributed from a central location and the rationale for the manner of distribution;
- 8) GSK's systems (including any centralized electronic systems), processes, policies, and procedures relating to speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;
- 9) GSK's systems, processes, policies, and procedures relating to engagement of "Consultants" (as defined in Section III.M.1 of the CIA) and all events and expenses associated with such activities;
- 10) GSK's systems, processes, policies, and procedures relating to GSK's funding, directly or indirectly, of Third Party Educational Activities for HCPs (as defined in Section II.C.8 of the CIA) and all events and expenses relating to such activities;
- 11) GSK's systems, processes, policies, and procedures relating to the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product ("Compendia"). This includes any initial submission of information to any Compendia and the submission of any

additional, updated, supplemental, or changed information, (e.g., any changes based on GSK's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia). The review shall also assess GSK's processes relating to its annual review of all arrangements, processing fees, or other payments or financial support (if any) provided to any Compendia;

12) GSK's systems, processes, policies, and procedures relating to Research and Publication Practices (as defined in Section III.B.3.u of the CIA), including the decision to provide financial or other support for such Research; the manner in which Research support is provided; the publication of information about the Research, including the publication of information about the Research results and trial outcomes, and uses made of publications relating to such research;

13) GSK's systems, processes, policies and procedures relating to authorship of any journal articles or other publications about GSK-Sponsored Research or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all financial relationships between the author and GSK, the identification of all authors or contributors (including professional writers, if any) associated with a given publication, and the scope and breadth of research results made available to each author or contributor;

14) GSK's systems, policies, processes, and procedures applicable to the manner and circumstances under which GSK personnel (including sales personnel (if any), personnel from the PPV Unit, MSLs, HOLs, or analogous personnel) participate in meetings with Payers (as defined in Section II.C.6 of the CIA) regarding Government Reimbursed Products and the role of the GSK personnel at such meetings; and

15) the form and content of information and materials disseminated by GSK to Payers and GSK's systems, policies, processes, and procedures relating to GSK's internal review and approval of information and materials related to Government Reimbursed Products disseminated to Payers by GSK.

## B. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of GSK's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-15 above, including a general description of GSK's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
- 3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-15 above are made known or disseminated within GSK;
- 4) a detailed description of any system(s) used to track and respond to requests for information about Government Reimbursed Products (including the Inquiries Database);
- 5) findings and supporting rationale regarding any weaknesses in GSK's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
- 6) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

### III. IRO Transactions Review

As described more fully below in Sections III.A-F, the Transactions Review for the second through sixth IRO Reporting Periods shall include: (1) a review of a sample of Inquiries reflected in the Inquiries Database; (2) a review of GSK's Target Plans and GSK's Target Plan review process; (3) a review of Sampling Events as defined below in Section III.C; (4) a review of records relating to a sample of the Payments that are reported by GSK pursuant to Section III.O of the CIA; (5) a review of Research and Publication Practices and Authorship-Related Practices; and (6) a review of up to three additional items identified by the OIG in accordance with Section III.E.1.b of the CIA

(hereafter “Additional Items”). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

For purposes of the Transactions Review for the first IRO Reporting Period, the Transactions Review shall include a review of Items 1-3 outlined in the preceding paragraph. The Transaction Review Report for the first IRO Reporting Period shall report on Items 1-3 in accordance with Section III.G below.

A. Review of Inquiries and Inquiries Database

1) Description of Inquiries Database

As set forth in Section III.B.3.g of the CIA, GSK shall establish a database to track information relating to requests for information received by GSK about its Government Reimbursed Products (hereafter “Inquiries”). Specifically, GSK shall document and record all Inquiries received from HCPs or HCIs regarding Government Reimbursed Products in a database(s) (the “Inquiries Database”). GSK shall record in the Inquiries Database the following information for each Inquiry received: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, medical information request form); 3) name of requesting HCP or HCI or other individual or entity; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about an off-label indication for the product; 6) nature/form of the response from GSK (including a record of any materials provided in response to the request); and 7) the name of the GSK representative who called upon or interacted with the HCP or HCI.

2) Internal Review of Inquiries Database

On a semi-annual basis, the Compliance Officer or designee shall review the Inquiries Database and related information, as appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters (“Inquiry Report”). The Compliance Officer or designee shall review the Inquiry Reports to assess whether the information contained in the report suggests that improper off-label promotion may have occurred in connection with any Inquiry(ies). If the Compliance Officer or designee, in consultation with other appropriate GSK personnel, suspects that improper off-label promotion may have occurred in connection with any Inquiry, the

Compliance Officer or designee shall undertake a follow-up review of the Inquiry (Off-Label Review), make specific findings based on his/her Off-Label Review, and take all appropriate responsive action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.J of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of 50 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period. Forty of the Inquiries reviewed by the IRO shall be Inquiries for which GSK conducted an Off-Label Review, and the other ten shall be Inquiries for which GSK did not conduct an Off-Label Review. For each Inquiry reviewed, the IRO shall determine:

- a) Whether each item of information listed above in Section III.A.1 is reflected in the Inquiries Database for each reviewed Inquiry; and
- b) For each Inquiry for which the Compliance Officer conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by GSK based on the Off-Label Review findings.

B. IRO Review of GSK's Target Plans and Target Plan Review Process

The IRO shall conduct a review and assessment of GSK's review of its Target Plans for Government Reimbursed Products as set forth in Section III.B.3.j of the CIA. GSK shall provide the IRO with: i) a list of Government Reimbursed Products promoted by GSK during the IRO Reporting Period; ii) information about the FDA-approved uses for each such product; and iii) the Target Plans for each such product. GSK shall also provide the IRO with information about the reviews of Target Plans that GSK conducted during the relevant IRO Reporting Period and any modifications to the Target Plans made as a result of GSK's reviews.

For each Target Plan, the IRO shall select a sample of 50 of the HCPs and HCIs included on the Target Plan. For each Target Plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by GSK

in conducting its review and/or modifying the Target Plan. The IRO shall seek to determine whether GSK followed its criteria and Policies and Procedures in reviewing and modifying the Target Plan.

The IRO shall note any instances in which it appears that the sampled HCPs or HCIs on a particular Target Plan are inconsistent with GSK's criteria relating to the Target Plan and/or GSK's Policies and Procedures. The IRO shall also note any instances in which it appears that GSK failed to follow its criteria or Policies and Procedures.

C. IRO Review of the Distribution of Samples of GSK Government Reimbursed Products

The IRO shall conduct a review and assessment of the distribution of samples of Government Reimbursed Products to HCPs and HCIs. GSK shall provide the IRO with: i) a list of Government Reimbursed Products for which GSK distributed samples during the IRO Reporting Period; ii) information about the FDA-approved uses for each such product; and iii) information about GSK's Sample Distribution Policies and Procedures, including GSK's exclusion lists showing which types of samples may not be distributed by sales personnel or other GSK personnel to HCPs and HCIs of particular medical specialties or types of clinical practices. GSK shall also provide the IRO with information about the reviews of Sample Distribution Policies and Procedures that GSK conducted during the IRO Reporting Period as set forth in Section III.B.3.k of the CIA and any modifications to the Sample Distribution Policies and Procedures or exclusion lists made as a result of GSK's reviews.

For each Government Reimbursed Product for which GSK distributed samples during the IRO Reporting Period, the IRO shall randomly select a sample of 50 separate instances in which GSK provided samples of the product to HCPs or HCIs. Each such instance shall be known as a "Sampling Event."

For each Sampling Event, the IRO shall review all documents and information relating to the distribution of the sample to the HCP or HCI. The reviewed materials shall include materials about the following: 1) the quantity, dosage, and form of the GSK product provided to the HCP or HCI; 2) the identity and type of medical specialty or clinical practice of the HCP or HCI; 3) which individual GSK sales personnel or other GSK personnel provided the sample to the HCP or HCI; and 4) the manner and mechanism through which the sample was requested (e.g., sample request form, letter, or call to GSK).

For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the Government Reimbursed Product approved by the FDA and whether the sample was distributed by an GSK representative in a manner consistent with GSK's sample distribution policy for the product(s) provided during the Sampling Event. To the extent that a sample was provided to an HCP or HCI by a GSK representative other than a sales personnel, the IRO shall contact the HCP or HCI by letter. The letter shall request that the HCP or HCI: 1) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; 2) verify that he/she/it requested the samples provided during the Sampling Event; 3) explain or confirm its type of medical specialty or clinical practice; and 4) identify the basis for requesting the sample (e.g., conversations with a GSK sales representative, conversation with a GSK representative at headquarters, independent research, or knowledge of the HCP or HCI).

For each Sampling Event, the IRO shall compare the medical specialty and type of clinical practice of the HCPs and HCIs that received the sample with uses of the Government Reimbursed Product approved by the FDA. The IRO shall note any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the Government Reimbursed Product approved by the FDA. For each such situation, the IRO shall note the process followed by GSK in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination. The IRO shall also note any instances in which it appears that GSK failed to follow its Sample Distribution Policies and Procedures for the Government Reimbursed Product(s) provided during the Sampling Event.

#### D. IRO Review of Physician Payment Listings

##### 1. Information Contained in Physician Payment Listings

For purposes of the IRO review as set forth in this Section III.D, each annual listing of physicians and Related Entities who received Payments (as defined in Section III.O of the CIA) from GSK shall be referred to as the "Physician Payment Listing" or "Listing." For each physician and Related Entity, each Physician Payment Listing shall include the following information: i) physician's full name; ii) name of Related Entity (if applicable); iii) city and state of the physician's practice or the Related Entity; and (iv) the aggregate value of the Payment(s) in the preceding year(s).

For purposes of this IRO review, the term "Control Documents" shall include all documents or electronic records associated with each Payment reflected in the Physician

Payments Listing for a sampled physician and/or Related Entity. For example, the term “Control Documents” includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the Listing; contracts relating to the Payment(s) reflected in the Listing; documents relating to the occurrence of Payment(s) reflected in the Listing; documents reflecting any work product generated in connection with the Payment(s); documents submitted by field personnel or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

## 2. Selection of Sample for Review

For each IRO Reporting Period, the OIG shall have the discretion to identify up to 50 physicians or Related Entities from the applicable Physician Payment Listing that will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO at least 90 days prior to the end of the IRO Reporting Period, of the physicians and/or Related Entities subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 physicians and/or Related Entities to be included in the review. For each selected physician and/or Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in the Listing identified by the IRO as necessary and sufficient to validate the Payment information in the Listing.

## 3. IRO Review of Control Documents for Selected Physicians and/or Related Entities

For each physician and/or Related Entity selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:

- a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;
- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in GSK’s policies;
- c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician is consistent with the

value of the Payments(s) reflected in the Control Documents;  
and

- d) Whether the Control Documents reflect that GSK's policies were followed in connection with Payment(s) reflected in the Listing (e.g., all required written approvals for the activity were obtained in accordance with GSK's policies).

4. Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:
  - i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
  - ii. the IRO cannot confirm that GSK otherwise followed its policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, including its policies and procedures relating to any Payment(s) reflected in the Listing; or
- b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with GSK's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but GSK has initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that GSK otherwise followed its policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

E. IRO Review of Research and Publications Practices and Authorship-Related Activities

The IRO shall conduct a review and assessment of GSK's Research and Publications Practices and Authorship-Related Activities as described in Sections III.B.3. u-v of the CIA.

Review of Research Activities: GSK shall provide the IRO with a list of all Research activities (as defined in Section III.B.3.u of the CIA) that were "active" (as classified in GSK's tracking system) during the IRO Reporting Period, and the IRO shall select a sample of 40 such activities, which sample shall include a review of each type of Research (*i.e.*, GSK-Sponsored post-marketing clinical trials, other GSK-Sponsored post-marketing studies, and post-marketing investigator-sponsored studies (ISSs).) The IRO shall review samples of each type of Research in proportion to the relative number of each type of Research that occurred during the reporting period. GSK shall provide the IRO with documents relating to the Research activities sufficient for the IRO to conduct the reviews outlined below.

For each sampled Research activity, the IRO will review whether: (i) the activity was approved consistent with GSK's standards, policies, procedures and processes regarding sponsorship or support of Research, including obtaining required approval for the Research by GSK's medical and/or research organizations and ensuring that the Research was conducted for the purpose of fostering increased understanding of scientific, clinical or medical issues; (ii) there is an executed written agreement with the Researcher that meets the requirements of GSK's standards, policies and procedures and, among other things, requires the Researcher to disclose in any publication of Research, GSK's support and any financial interest the researcher may have in GSK; and (iii) GSK's sales, marketing, or other commercial personnel did not participate in the design, conduct, or publication of the Research activity except as permitted under the limited exceptions in GSK's policies and procedures.

Review of Publication Activities:

GSK shall provide the IRO with a list of publication activities (as defined in Section III.M.3 of the CIA) that resulted in publication of data from GSK-Sponsored post-marketing clinical trials or post-marketing studies of Government Reimbursed Products that appeared during the IRO Reporting Period. The list will be broken down into two categories: (i) GSK-Sponsored post-marketing clinical trials, and (ii) other GSK-Sponsored post-marketing studies (*e.g.*, observational studies, health outcomes studies, epidemiology studies, and meta-analyses and pooled analyses.) The IRO shall select a sample from each category for review, in proportion to the relative numbers in each category (collectively, “Reviewed Publication Activities”). The IRO shall review a total of 60 Reviewed Publication Activities. GSK shall provide the IRO with copies of the publications and documents and information relating to each of the Reviewed Publication Activities sufficient for the IRO to conduct the reviews outlined below.

The IRO will assess each of the Reviewed Publication Activities to test whether the Reviewed Publication Activity was conducted in a manner consistent with GSK’s standards, policies, procedures and processes, including those that require: i) posting of summary results from all GSK-Sponsored post-marketing interventional research studies of Government Reimbursed Products on GSK’s Clinical Study Register within a specified periods of time; ii) posting of summaries of study protocols for such research studies in the GSK Clinical Study Register; iii) registration of summary results from applicable GSK-Sponsored clinical trials on the NIH sponsored website in compliance with all Federal requirements; iv) publication (or attempted publication) of the results of GSK-Sponsored post-marketing interventional Research studies in peer-reviewed journals within specified periods of times; and v) compliance with GSK’s operating practices regarding publications relating to GSK-Sponsored post-marketing interventional research studies of Government Reimbursed Products (including standards relating to appropriateness, accuracy, balance, and acknowledgement of GSK’s role as the funding source for the Research).

#### Review of Authorship-Related Activities:

For each of the Reviewed Publication Activities, the IRO shall also assess the activity to test whether the activity was conducted in a manner consistent with GSK’s standards, policies, procedures and processes relating to authorship, including those that require: i) authors of journal articles about GSK-Sponsored Research to adhere to ICMJE authorship requirements (except in instances in which a particular journal requires an alternative procedure); ii) authors of articles on GSK-Sponsored Research to disclose any GSK financial support for the study and any financial relationship with GSK; iii) authors of a GSK publication of GSK-Sponsored Research to make substantial contributions to the study and give final approval to the version of the publication ultimately published;

and iv) certifications from employees and medical writing contractors as to any GSK publication of GSK-Sponsored Research on which the individual is listed as an author or contributor.

#### F. IRO Review of Additional Items

As set forth in Section III.E.1.b of the CIA, for the second through sixth IRO Reporting Periods, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter “Additional Items”). No later than 150 days prior to the end of the applicable IRO Reporting Period, the OIG shall notify GSK of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or GSK shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO’s findings based on its review for each Additional Item; and the IRO’s recommendations for any changes in GSK’s systems, processes, policies, and procedures based on its review of each Additional Item).

GSK may propose to the OIG that its internal audit(s) be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable IRO Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow GSK’s internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of GSK’s planned internal audit work, the results of the Transactions Review(s) during prior IRO Reporting Period(s), and GSK’s demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies GSK’s request to permit its internal audit work to be substituted for a portion of the IRO’s review of Additional Items in a given IRO Reporting Period, GSK shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of GSK’s internal audit work for a given IRO Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review,

the IRO shall review at least 20% of the sampling units reviewed by GSK in its internal audits.

G. Transactions Review Report

For each IRO Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

- 1) General Elements to Be Included in Report
  - a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
  - b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
  - c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

2) Results to be Included in Report

Consistent with the scope of items reviewed by the IRO for the applicable IRO Reporting Period, the following results shall be included in each Transaction Review Report:

(Relating to the Review of Inquiries)

- a) in connection with the review of Inquiries, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (e.g., the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;
- b) for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the Inquiries Database;

- c) for each Inquiry sample unit, findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the Inquiries Database; and (ii) for each Inquiry for which an Off-Label Review was conducted, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by GSK as a result of the Compliance Officer's findings;
- d) the findings and supporting rationale regarding any weaknesses in GSK's systems, processes, policies, procedures, and practices relating to the Inquiries, and the Inquiries Database, if any;
- e) recommendations for improvement in GSK's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

(Relating to the Target Plan Reviews)

- f) a list of the Government Reimbursed Products promoted by GSK during the IRO Reporting Period and a summary of the FDA-approved uses for such products;
- g) for each Government Reimbursed Product which was promoted during the IRO Reporting Period: i) a description of the criteria used by GSK in developing or reviewing the Target Plans and for including or excluding specified types of HCPs or HCIs from the Target Plans; ii) a description of the review conducted by GSK of the Target Plans and an indication of whether GSK reviewed the Target Plans as required by Section III.B.3.j of the CIA; iii) a description of all instances for each Target Plan in which it appears that the HCPs and HCIs included on the Target Plan are inconsistent with GSK's criteria relating to the Target Plan and/or GSK's Policies and Procedures; and iv) a description of all instances in which it appears that GSK failed to follow its criteria or Policies and Procedures relating to Target Plans or the review of the Target Plans;
- h) the findings and supporting rationale regarding any weaknesses in GSK's systems, processes, policies, procedures, and practices

relating to GSK's Target Plans or the review of the Target Plans, if any;

- i) recommendations, if any, for changes in GSK's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to Target Plans or the review of the Target Plans;

(Relating to the Sampling Event Reviews)

- j) for each Government Reimbursed Product distributed during the IRO Reporting Period: i) a description of Sample Distribution Policies and Procedures (including whether sales representatives may provide samples for the product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice a sales representative may provide samples); ii) a detailed description of any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event was not consistent with the uses of the product approved by the FDA. This description shall include a description of the process followed by GSK in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and iii) a detailed description of any instances in which it appears that GSK failed to follow its Sample Distribution Policies and Procedures for the Government Reimbursed Product(s) provided during the Sampling Event;
- k) the findings and supporting rationale regarding any weaknesses in GSK's systems, processes, policies, procedures, and practices relating to GSK's distribution of samples of Government Reimbursed Products, if any;
- l) recommendations, if any, for changes in GSK's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples;

(Relating to the Physician Payment Listing Reviews)

- m) a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;
- n) for each sampled physician or Related Entity, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable GSK policy; (iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that GSK's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (v) disciplinary action was undertaken in those instances in which GSK policies were not followed;
- o) for each sampled physician or Related Entity unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action;
- p) if any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

(Relating to the Review of Research and Publication Practices and Authorship-Related Activities)

- q) a description of each sampled Research activity reviewed, including an identification of the types of documents and information reviewed in connection with each sampled Research activity;
- r) an assessment of whether, for each sampled Research activity: (i) the activity was approved consistent with GSK's standards, policies, procedures and processes regarding sponsorship or support of Research; (ii) there is an executed written agreement with the

Researcher that meets the requirements of GSK's standards, policies and procedures; and (iii) GSK's sales, marketing, or other commercial personnel did not participate in the design, conduct, or publication of the Research Activity except as permitted under GSK's policies and procedures. If a sampled Research activity failed to meet GSK standards, policies, procedures and processes, an explanation of the deficiency;

- s) a description of each Reviewed Publication Activity assessed by the IRO, including an identification of the types of documents and information reviewed in connection with each Reviewed Publication Activity;
- t) an assessment of whether for each Reviewed Publication Activity; i) authors of journal articles about GSK-Sponsored Research adhered to ICMJE requirements; ii) authors of articles about GSK-Sponsored Research disclosed any GSK financial support for the study and any financial relationship with GSK; iii) authors of a GSK publication about GSK-Sponsored Research made substantial contributions to the study and gave final approval to the version of the publication ultimately published; and iv) GSK obtained certifications from employees, medical writing contractors, and outside authors as to any GSK publication of GSK-Sponsored Research on which the individual is listed as an author or contributor;
- u) an assessment of whether for each Reviewed Publication Activity; i) authors of journal articles about GSK-Sponsored Research adhered to ICMJE requirements; ii) authors of articles on GSK-Sponsored Research disclosed any GSK financial support for the study and any financial relationship with GSK; iii) authors of a GSK publication of GSK-Sponsored Research made substantial contributions to the study and gave final approval to the version of the publication ultimately published; and iv) GSK obtained certifications from employees, medical writing contractors, and outside authors as to any GSK publication of GSK-Sponsored Research on which the individual is listed as an author or contributor;
- v) if any Reviewed Publication Activity failed to meet GSK standards, policies, procedures and processes, an explanation of the deficiency;

- w) the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in GSK's systems, processes, policies, procedures, and practices relating to GSK's Research and Publications Practices and Authorship-Related Activities, if any;
- x) recommendations, if any, for changes in GSK's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to Research and Publications Practices and Authorship-Related Activities;

(Relating to the Review of Additional Items)

- y) for each Additional Item reviewed, a description of the review conducted;
- z) for each Additional Item reviewed, the IRO's findings based on its review;
- aa) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in GSK's systems, processes, policies, procedures, and practices relating to the Additional Item, if any;
- bb) for each Additional Item reviewed, recommendations, if any, for changes in GSK's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

**Appendix C to CIA for GlaxoSmithKline LLC**  
**IRO Reviews of GSK's Targeted Risk Analysis and**  
**Compliance Evaluation Review (TRACER) Program**

I. General Description of TRACER program

GSK uses the Targeted Risk Analysis and Compliance Evaluation Review process (TRACER) as a tool to evaluate and mitigate promotional risks (hereinafter, "risks") associated with all prescription Government Reimbursed Products that have field force support in the United States (GSK Products).

*1. Risk Identification and Evaluation*

As part of TRACER, risk information will be solicited from four key sources: (i) Copy Approval Teams; (ii) U.S. Pharma's Monitoring Control Center of Excellence (CCoE); (iii) Deputy Compliance Officers (DCOs); and (iv) Legal department personnel.

Based on inputs from these sources, a relative risk ranking report will be produced for all GSK Products (Risk Evaluation Report). The Risk Evaluation Report will be presented to the leadership team of each U.S. Pharma commercial business unit (Leadership Team) and the U.S. Pharma Commercial Leadership Team (CLT) along with recommendations regarding which products may require enhanced risk mitigation plans.

The Risk Evaluation Report will also be used by the CCoE to inform the risk-based selection of products as required by the Field Force Monitoring Program described in CIA Section III.L.

*2. Risk Mitigation Plans*

Risk Mitigation Plans (RMPs) will be completed annually for all GSK Products. All RMPs will outline standard risk mitigation activities that will be performed and tracked for each GSK Product, regardless of the product's relative risk ranking (Standard RMPs). Standard risk mitigation activities will consist of the monitoring activities to be conducted for each GSK Product in the upcoming year, such as monitoring of speaker programs, speaker training, advisory boards, sampling, verbatim reviews, medical information requests and ride-alongs with sales personnel.

Based on the Risk Evaluation Report, products may be selected for Enhanced RMPs by either (or both) the Leadership Teams and the CLT. These RMPs will include enhanced risk mitigation activities, in addition to the standard activities (Enhanced RMPs). Enhanced RMPs will consist of activities tailored to the risks identified during the risk ranking process. For example, such activities may include increased compliance

messaging from Leadership Teams, modifications to or limitations of promotional programs, or enhanced training requirements.

All RMPs (whether Standard or Enhanced) will be developed by brand teams, in consultation with their respective DCOs and the CCoE, on an annual basis. Each RMP will specify the: (i) risk monitoring activities; (ii) metrics by which monitoring activities and results will be evaluated and/or measured; (iii) risk mitigation action items, if necessary; (iv) metrics by which risk mitigation activities and results will be evaluated and/or measured; (v) responsible individual(s); and (vi) expected date(s) of monitoring and/or action item completion. The RMPs will be reviewed and approved by the respective business unit Leadership Teams.

### 3. *Risk Mitigation Plan Tracking*

RMP activities (including risk monitoring activities, risk mitigation activities, and risk mitigation action items) will be tracked by the CCoE and reported using a Monitoring Dashboard which will identify risk monitoring and mitigation activities and track their progress on at least a quarterly basis. The status of the RMPs will be tracked and reported to Leadership Teams and compliance personnel on at least a quarterly basis.

## II. TRACER Reviews, General Description

A. As specified more fully below, GSK shall retain an IRO to assist GSK in assessing and evaluating its systems, processes, policies, procedures, and practices relating to the TRACER program (TRACER Review). The TRACER Review shall consist of two components - a systems review (TRACER Systems Review) and a transactions review (TRACER Transactions Review) as described more fully below. GSK may engage, at its discretion, a single IRO to perform both components of the TRACER Review provided that the entity has the necessary expertise and capabilities to perform both.

B. If there are no material changes in GSK's systems, processes, policies, and procedures relating to TRACER, the IRO shall perform the TRACER Systems review for the second and fifth IRO Reporting Periods. If GSK materially changes its systems, processes, policies, and procedures relating to TRACER, the IRO shall perform a TRACER Systems Review for the IRO Reporting Period(s) in which such changes were made in addition to conducting the Systems Review for the second and fifth IRO Reporting Periods. The additional TRACER Systems Review(s) shall consist of: (1) an identification of the material changes; (2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and (3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the TRACER Transactions Review for second through sixth IRO Reporting Periods of the CIA.

### III. TRACER Systems Review

#### A. The TRACER Systems review shall consist of the following:

1. A review of the processes by which GSK develops and evaluates Risk Evaluation Reports and develops Standard and Enhanced RMPs, including the sources of information (e.g., the individual personnel, departments or functional areas, and/or any systems involved) used to compile the Reports and RMPs; the types of underlying data and information that are considered or evaluated during the development of the Risk Evaluation Reports and the RMPs; and the timing for development of Risk Evaluation Reports and the RMPs (including modifications to the Reports or RMPs in the event of significant new developments);
2. An assessment of whether, in developing the Risk Evaluation Reports and the RMPs: i) additional or different sources of information; ii) additional or different types of data or information; and iii) additional or different timing cycles should be utilized;
3. A review of the experience and background of the brand directors responsible for development of the RMPs and an assessment of the completeness and appropriateness of the training, policies, procedures, standard operating procedures, and guidance such individuals receive regarding the development of the RMPs;
4. An assessment of whether the standard risk mitigation activities (monitoring activities) included in RMPs are designed to: (i) adequately monitor all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iii) ensure that the activity associated with an identified risk does not occur in the future;
5. An assessment of whether standard risk mitigation activities (monitoring activities) that may be included in RMPs should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific products reviewed;

6. An assessment of whether enhanced risk mitigation activities and risk mitigation action items (and options for such activities) included in Enhanced RMPs are designed to: (i) adequately address all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iii) ensure that the activity associated with an identified risk does not occur in the future;
7. An assessment of whether enhanced risk mitigation activities that may be included in RMPs should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific products reviewed; and
8. A review of the systems, policies, procedures, and processes (including the Monitoring Dashboard and any narrative supplements) by which GSK tracks and manages RMP activities and an assessment of whether the systems, policies, procedures and processes ensure that the RMPs are appropriately implemented (including by identifying individuals responsible for the follow-up or action items).

B. The IRO shall prepare a report based upon each Systems Review performed (System Review Report). The Systems Review Report will include the IRO's findings, recommendations, observations, and comments on items 1-8 above and, to the extent not otherwise addressed, an assessment of the following: (i) whether the Risk Evaluation Reports and RMPs identify and prioritize relevant risks; (ii) whether the risk monitoring activities, risk mitigation activities and any risk mitigation action items identified in RMPs address identified risks; (iii) whether sufficient controls exist to ensure that all risk mitigation steps (including monitoring activities and risk mitigation activities) are completed in accordance with the RMPs; iv) whether the options for risk monitoring activities and risk mitigation activities identified in the RMPs address and potentially mitigate identified risks; and (iv) whether sufficient controls exist to ensure that all agreed-upon risk monitoring activities and risk mitigation activities are completed in accordance with the RMPs.

#### IV. TRACER Transactions Review

A. At least thirty (30) days prior to the end of the second through sixth IRO Reporting Periods, GSK shall submit to OIG a list of all GSK Products for which RMPs were developed. GSK shall notify the OIG about which products had Standard RMPs and which products had Enhanced RMPs. Prior to the end of the applicable IRO

Reporting Period, OIG shall select 3 GSK Products (each a “Selected Product” and together the “Selected Products”) to be reviewed in connection with the TRACER Transactions Review.

B. For each IRO Reporting Period and for each Selected Product, the IRO shall conduct a review of: i) the applicable Risk Evaluation Report entry and RMP; ii) documents and materials related to the development of the RMP; and iii) documents and materials relating to the implementation of the RMP (including the Monitoring Dashboard and any supplements to the Scorecard). The IRO shall also interview the brand team director responsible for the development of the RMP and the individual(s) responsible for the implementation of the risk monitoring and risk mitigation activities specified in the RMP.

The objective of the IRO shall be to: (i) understand the processes followed by GSK in developing the RMP for each Selected Product, including the underlying bases for GSK’s decision to develop either a Standard RMP or an Enhanced RMP for the Selected Product; (ii) determine whether, based on the information contained in the Risk Evaluation Report, an appropriate RMP (including as to the included risk monitoring activities, risk mitigation activities, and risk mitigation action items) was developed for the Selected Product; and (iii) assess GSK’s implementation and tracking of the implementation of the RMP for the Selected Product.

C. The IRO will prepare a report based on each TRACER Transactions Review performed (Transactions Review Report). The Transactions Review Report shall include the following:

1. an identification of the 3 Selected Products and a description of the documents and information reviewed in connection with each Selected Product, including a description of whether the RMP for each Selected Product was a Standard RMP or an Enhanced RMP,
2. for each Selected Product, a description of: i) the process followed in developing the RMP; and ii) the types of identified risks associated with the Selected Product;
3. for each Selected Product, an assessment of whether it was appropriate for GSK to develop, as applicable, an Enhanced or a Standard, RMP for the product;
4. for each Selected Product, an assessment of whether, based on the information contained in the Risk Evaluation Report, an appropriate RMP was developed for the Selected Product;

5. for each Selected Product, a description of the expertise and backgrounds of the brand directors who were responsible for the development of the RMP;
6. for each Selected Product, a description of the following items set forth in the RMP: (i) risk monitoring activities; (ii) metrics by which the risk monitoring activities and results will be evaluated and/or measured; (iii) risk mitigation activities, including any risk mitigation action items; (iv) metrics by which the risk mitigation activities and results will be evaluated and/or measured; (v) responsible individual(s); (vi) expected date(s) of completion for each risk monitoring activity and risk mitigation activity; and (vii) if the RMP did not specify each of the items set forth above, a description of any deficiencies;
7. for each Selected Product, a description of whether risk monitoring activities specified in the RMP were implemented and tracked in accordance with the RMP and GSK's policies and procedures, and a description of any deficiencies;
8. for each Selected Product, a description of whether risk mitigation activities (including any action items) specified in the RMP were implemented and tracked in accordance with the RMP and GSK's policies and procedures, and a description of any deficiencies;
9. for each Selected Product a description of: (i) any recommendations made by the IRO regarding the RMP or any risk monitoring activities and risk mitigation activities included in the RMP; (ii) whether, and in what manner, GSK implemented the recommendations from the IRO; and (iii) if GSK did not implement the IRO recommendations, a description of the rationale for GSK's decision not to implement the recommendations; and
10. the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in GSK's systems, processes, policies, procedures, and practices relating to the TRACER program, if any; and recommendations, if any, for changes in GSK's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the TRACER program.

## **Appendix D to CIA for GlaxoSmithKline LLC**

### **Global Manufacturing and Supply-Related Provisions**

#### **I. PREAMBLE**

Prior to the Effective Date of the CIA (as defined below), GSK and its Affiliates established a voluntary compliance program applicable to the Global Manufacturing and Supply business unit (GMS Compliance Program). GMS has responsibility for the compliance function at the manufacturing facility located in Zebulon, North Carolina (Zebulon) and at manufacturing facilities worldwide. GMS employees at Zebulon are responsible for the release and post-release management of all Covered Products (defined below in Section II.C.3) distributed in the United States that are either manufactured at the Zebulon site or manufactured at other manufacturing facilities operated by GMS and located outside of the United States.

The GMS Compliance Program includes a GMS Compliance Officer and a GMS Compliance Committee. The GMS Compliance Program also includes a Code of Conduct (as described in Section III.B.1 of the CIA), written policies and procedures, educational and training initiatives, a Disclosure Program that allows for the confidential disclosure and investigation of potential compliance violations and disciplinary procedures, screening measures for Ineligible Persons, and internal auditing procedures. GSK shall continue the GMS Compliance Program throughout the term of this Appendix and shall do so in accordance with the terms set forth below. GSK may modify its GMS Compliance Program as appropriate, but, at a minimum, GSK shall ensure that during the term of this Appendix, it shall comply with the obligations set forth in this Appendix.

#### **II. TERM AND SCOPE OF THIS APPENDIX**

A. Unless otherwise specified, the period of the compliance obligations assumed by GSK and its Affiliates under this Appendix D shall be five reporting periods, as defined below. The “Effective Date” shall be the date on which the final signatory of the CIA executes the CIA. The first Reporting Period shall be from the Effective Date through December 31, 2013. The second and subsequent Reporting Periods shall be from January 1 through December 31 of each of the subsequent four calendar years.

B. Sections III.D of this Appendix to the CIA and sections VII, X, and XI of the CIA shall expire no later than 120 days after OIG’s receipt of: (1) GSK’s final Annual Report with respect to this Appendix; or (2) any additional materials submitted by GSK pursuant to OIG’s request, whichever is later.

C. The scope of this Appendix shall be governed by the following definitions:

1. “Manufacturing Covered Persons” includes:

- a. President, Global Manufacturing and Supply;
- b. All members of the GMS Executive Team;
- c. Senior Vice President of GMS Quality;
- d. All members of the Quality Executive Team (QET);
- e. All “above-site” employees with a direct reporting line into a QET member, and whose responsibilities include managing GMS employees that directly support cGMP Activities at the Covered Manufacturing Facility(ies);
- f. The Site Quality Director at the Covered Manufacturing Facility(ies);
- g. All GSK employees at the Covered Manufacturing Facility(ies) who are engaged in cGMP Activities;
- h. Senior Vice President of GMS Pharma Operations;
- i. All above-site employees with a direct reporting line to the Senior Vice President of Pharma Operations whose responsibilities include managing manufacturing operations at the Covered Manufacturing Facility(ies);
- j. With respect to GMS manufacturing facilities (other than a Covered Manufacturing Facility) located in the United States that manufacture and/or release drug products for distribution in the United States, the Site Director, the Site Quality Director, and any employee who is directly responsible for authorizing the release for distribution of drug products at such GMS manufacturing facilities;
- k. With respect to GSK vaccines manufacturing facilities (other than a Covered Manufacturing Facility) located in the United States that manufacture and/or release vaccines for distribution in the United States, the Site Director, the Site Quality Director and any employee who is directly responsible for authorizing the release for distribution of vaccines at such vaccines manufacturing facilities;
- l. Any GSK employee at a distribution center located in the United States that is operated by or on behalf of GSK who is directly responsible for authorizing the release for distribution of drug products or vaccines from such distribution center; and
- m. Any contractor, subcontractor, agent or other person whose normal place of work is a Covered Manufacturing Facility(ies) and whose day-to-day responsibilities directly relate to cGMP Activities.

Notwithstanding the above, this term does not include employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per calendar year, except that any such individuals shall become “Manufacturing Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “cGMP Activities” means activities directly related to ensuring compliance with current Good Manufacturing Practice (cGMP) requirements contained in the Federal Food, Drug, and Cosmetic Act and applicable regulations (collectively “cGMP Requirements”), to submitting cGMP-related reports and information to the FDA, and/or responding to FDA inspectional observations or other correspondence, including correspondence regarding cGMP Requirements.

3. “Covered Products” means prescription drug products sold by GSK that are reimbursed by a Federal health care program and that are manufactured at a GSK facility and released by a Covered Manufacturing Facility (as defined below in Section II.C.4) or any other GSK facility for distribution into the United States. Vaccines are not Covered Products.

4. “Covered Manufacturing Facility” means the GSK facility in Zebulon, North Carolina, and subject to Section IV.A, any other GSK facility that after the Effective Date of this CIA and Appendix, manufactures, or is responsible for the release of Covered Products in the United States.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

To the extent not accomplished prior to the Effective Date, GSK shall establish and maintain a GMS Compliance Program that includes the following elements:

#### **A. Compliance Officer and GMS Compliance Committee**

1. *Compliance Officer.* Prior to the Effective Date, GSK appointed an individual to serve as a Compliance Officer for its GMS business unit (GMS Compliance Officer) and GSK shall maintain a GMS Compliance Officer for the term of this Appendix. The GMS Compliance Officer shall be responsible for overseeing the development and implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Appendix relating to cGMP Activities, with applicable Federal health care program requirements and applicable FDA requirements. The GMS Compliance Officer shall be a member of senior management of GMS, and shall report directly to the Senior Vice President for Governance, Ethics and Assurance of GlaxoSmithKline PLC, who, in turn reports to the Chief Executive Officer of GlaxoSmithKline PLC. The GMS Compliance Officer shall make periodic (at least quarterly) reports regarding GMS compliance matters related to this Appendix to the Board of Directors (or an authorized committee thereof) of GlaxoSmithKline PLC

(hereinafter, “the Board”), and shall be authorized to report on such matters to the Board at any time. The GMS Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The GMS Compliance Officer shall be responsible for oversight of the day-to-day compliance activities engaged in by GMS as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the GMS Compliance Officer shall be limited and must not interfere with the GMS Compliance Officer’s ability to perform the duties outlined in this CIA.

GSK shall report to OIG, in writing, any changes in the identity of the GMS Compliance Officer, or any actions or changes that would affect the GMS Compliance Officer’s ability to perform the duties necessary to meet the obligations in this Appendix, within 5 days after such a change.

2. *GMS Compliance Committee.* Prior to the Effective Date, GMS established a GMS Compliance Committee. The GMS Compliance Committee includes the GMS Compliance Officer and other members of GMS senior management necessary to meet the requirements of this Appendix. The GMS Compliance Officer shall co-chair the GMS Compliance Committee with the GMS President. The GMS Compliance Committee shall support the GMS Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the GMS’s cGMP risk areas and shall oversee monitoring of internal and external audits and investigations related to cGMP Requirements). The GMS Compliance Committee shall meet at least quarterly.

GSK shall report to OIG, in writing, any changes in the composition of the GMS Compliance Committee, or any actions or changes that would affect the GMS Compliance Committee’s ability to perform the duties necessary to meet the obligations in this Appendix, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* The Board shall be responsible for the oversight of matters related to compliance with cGMP Activities, applicable Federal health care program requirements, applicable FDA requirements, and the obligations of this Appendix.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee GMS’s Compliance Program, including but not limited to the performance of the GMS Compliance Officer and other GMS compliance personnel;
- b. for each Reporting Period of this Appendix, adopting a resolution, signed by each member of the Board summarizing its review and oversight of GMS’s compliance with cGMP Activities, applicable Federal health care program

requirements, applicable FDA requirements, and the obligations of this Appendix.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of the GMS Compliance Program for the time period [insert time period], including the performance of the GMS Compliance Officer. The Board has concluded that, to the best of its knowledge, GSK has implemented an effective Compliance Program, including a program that is effective to meet applicable Federal health care program requirements, applicable FDA requirements, and the obligations of this Appendix D to the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective GMS Compliance Program.

GSK shall report to the OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board’s ability to perform the duties necessary to meet the obligations in this Appendix, within 15 days after such change.

B. Written Standards

*Code of Conduct.* Prior to the Effective Date, GSK developed and adopted a written Code of Conduct (as described in Section III.B.1 of the CIA).

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall distribute the Code of Conduct to each Manufacturing Covered Person who is a GSK employee and each Manufacturing Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the Code of Conduct. New Manufacturing Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Manufacturing Covered Person or within 120 days after the Effective Date, whichever is later.

As provided in Section III.B of the CIA, GSK shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed to Manufacturing Covered Persons within 30 days to after any revisions are finalized. Each Manufacturing Covered Person shall certify, in writing or electronically, that he or she

has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

1. *Policies and Procedures.* Prior to the execution of the CIA, GSK implemented written Policies and Procedures regarding the operation of its GMS Compliance Program. Within 120 days after the Effective Date, GMS shall implement written procedures regarding any additional Compliance Program requirements outlined in this Appendix D. To the extent not already accomplished, within 120 days after the Effective Date, GMS shall ensure that the Policies and Procedures address or shall continue to address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1 of the CIA; and
- b. disciplinary policies and procedures for violations of the Company's Policies and Procedures, including policies relating to cGMP Activities and FDA requirements relating to cGMP Activities.

To the extent not already accomplished, within 120 days after the Effective Date, the Policies and Procedures shall be made available to all Manufacturing Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), GSK shall assess and update the Policies and Procedures, as necessary. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be made available to all Manufacturing Covered Persons.

#### C. Training and Education

GSK represents that it provides training on a regular basis concerning a variety of topics directly related to cGMP Activities. The training required by this Appendix need not be separate and distinct from the regular training provided by GSK to Manufacturing Covered Persons. At GSK's option, the training required by this Appendix may be integrated into the regular training provided by GSK.

1. *General Training.* Within 120 days after the Effective Date, GMS shall provide at least one hour of General Training to each Manufacturing Covered Person. This training, at a minimum, shall explain:

- a. The requirements of this Appendix D to the CIA; and

- b. GMS's Compliance Program, including the Company's Code of Conduct.

New Manufacturing Covered Persons shall receive the General Training described above within 30 days after becoming a Manufacturing Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Manufacturing Covered Person shall receive at least one hour of General Training during each subsequent Reporting Period.

*Board Member Training.* The training required by Section III.C.4 of the CIA shall include training on the obligations set forth in this Appendix.

2. *Certification.* Each individual who is required to receive training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training and the date upon which the training was completed. The GMS Compliance Officer (or designee) shall retain the certifications, along with all course materials.

3. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area, including about FDA requirements relating to cGMP Activities.

4. *Update of Training.* GMS shall review the content of each training program required by this Appendix annually and update the content of each training program, where appropriate, to reflect any material changes to cGMP requirements, changes to applicable Federal health care program requirements, FDA requirements, and any issues observed during internal audits.

5. *Computer-based Training.* GMS may provide the training required under this Appendix through appropriate computer-based training approaches. If GMS chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training. All applicable requirements to provide a number of "hours" of training as set forth in this Section III.C. may be met with respect to computer-based training by providing the required number of "normative" hours as that term is used in the computer-based training industry.

#### D. cGMP Requirements

1. In addition to existing FDA authorities and remedies, GSK agrees to certain obligations under this Appendix relating to cGMP Requirements for GSK drug products and vaccines. These provisions are in addition to other remedies available to the FDA.

2. If the Director of Compliance at FDA's Center for Drug Evaluation and Research (CDER), or in the case of a vaccine, the Director of Compliance at FDA's Center for Biologics Evaluation and Research (CBER) determines that a GSK facility (or facilities) manufacturing, processing, packing, or holding a GSK drug product or vaccine is not compliant with cGMP Requirements, FDA may so notify the OIG and recommend that OIG direct GSK to undertake a Specified Action as set forth below in section III.D.3 of this Appendix.

3. If, after reviewing FDA's notification and recommendation, OIG agrees that GSK should be directed to undertake a Specified Action as set forth in section III.D.3 of this Appendix, OIG shall notify GSK in writing of its determination and direct GSK to undertake one or more of the following actions (Specified Actions):

- a. Submit a report or information addressing the assertion of non-compliance to FDA and OIG within 10 days after the date of written notification from the OIG in accordance with the Notification provision in section III.D.4 below;
- b. In the event that OIG and/or FDA request additional or follow-up information, GSK shall submit revised, modified, or expanded report(s) or plan(s) to FDA and OIG in accordance with time frames established by the OIG and FDA; and/or
- c. Initiate a recall of the GSK drug product or vaccine in accordance with the instructions and time frames specified by OIG and FDA.

4. All notifications and reports required under this Section III.D shall be submitted to the following:

OIG

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201

FDA

Division of Manufacturing and Product Quality  
HFD-320  
Center for Drug Evaluation and Research  
10903 New Hampshire Avenue  
White Oak Bldg. 51  
Silver Spring, MD 20993

GSK

Guy Wingate  
Vice President - GMS Compliance Officer  
GlaxoSmithKline  
GSK House (Mailstop BNG-15)  
980 Great West Road  
Brentford  
Middlesex  
TW8 9GS  
United Kingdom

Paul Noll  
Vice President - Associate General Counsel  
Legal Operations - Global Manufacturing and Supply  
GlaxoSmithKline  
Five Moore Drive  
Ruvane Building - Mailstop E.3334  
Research Triangle Park, NC 27709

5. Within 10 days after receiving notification from the OIG of a Specified Action to be taken, GSK shall notify OIG and FDA in writing either:
- a. that GSK is undertaking or has undertaken the Specified Action, in which event GSK also shall describe the Specified Action taken or to be taken and the schedule for completing the action; or
  - b. that GSK does not agree with the OIG's determination that it failed to comply with cGMP Requirements and/or that the Specified Action is appropriate.

6. If GSK notifies OIG and FDA that it does not agree with the determination that it failed to comply with cGMP Requirements or that the Specified Action is appropriate:

- a. GSK shall explain in writing the basis for its disagreement; in so doing, GSK also may propose specific alternative actions and specific time frames to be substituted for the Specified Action required under this Section III.D.
- b. FDA shall review GSK's notification and thereafter, in writing, make a recommendation to OIG that OIG affirm, modify, or withdraw its proposed Specified Action.

7. Based on the advice of the FDA, OIG shall decide whether the determination that GSK failed to comply with cGMP Requirements and/or the proposed Specified Action shall be affirmed, modified, or withdrawn and shall provide written notice (Final Determination) to GSK of the Specified Action to be taken or of the withdrawal of the Specified Action. GSK shall, upon receipt of the notification of Final Determination, immediately implement the Final Determination.

8. GSK's failure to implement that Specified Action shall be the basis for Stipulated Penalties and or Material Breach Penalties under Section X of the CIA.

#### E. Manufacturing Reportable Events

1. *Definition of Manufacturing Reportable Event.* For purposes of this Appendix, a "Manufacturing Reportable Event" means conduct related to a Covered Manufacturing Facility or Covered Product that involves:

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to cGMP Activities; or
- b. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a of the CIA;

A Manufacturing Reportable Event may be the result of an isolated event or a series of occurrences. A Manufacturing Reportable Event does not include the following:

- a. Field Alert Reports submitted to FDA and related correspondence;

- b. Observations contained in FDA 483 Reports, GSK's responses to those observations and any related correspondence;
- c. Drug Quality Reporting System (DQRS) reports submitted to FDA and any related correspondence;
- d. Reports submitted to FDA relating to suspected or known counterfeit products and any related correspondence; and
- e. GSK Annual Product Reports for marketed products submitted to FDA and any related correspondence.

2. *Reporting of Manufacturing Reportable Events.* If GSK determines (after a reasonable opportunity to conduct an appropriate review or investigation) through any means that there is a Manufacturing Reportable Event, GSK shall, notify OIG in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Manufacturing Reportable Events under Section III.E.1.a-b.* For Manufacturing Reportable Events under Sections III.E.1.a-c, the report to OIG shall include:

- a. a complete description of the Manufacturing Reportable Event, including the relevant facts and persons involved and the legal authorities implicated;
- b. a description of GSK's actions taken to correct the Manufacturing Reportable Event; and
- c. any further steps GSK plans to take to address the Manufacturing Reportable Event and prevent it from recurring.

F. Reporting of Certain Events

If GSK voluntarily initiates a recall of a Covered Product manufactured at and/or released by either a Covered Manufacturing Facility or other GSK manufacturing facility located in the United States and that has been distributed in the United States, GSK shall notify OIG in writing within 5 days after initiating the recall.

**IV. CHANGES TO BUSINESS UNITS OR LOCATIONS**

Change of Status of a Covered Manufacturing Facility. In the event that, after the Effective Date, a new GSK facility located in the United States other than, or in

addition to, the Zebulon, North Carolina facility, manufacturers and/or releases for distribution in the United States Covered Products sold by GSK that are reimbursed by Federal health care programs, such facility may become a Covered Manufacturing Facility subject to the terms described below. As of the date that such new facility commences manufacture and/or release of a Covered Product, the Site Director, the Site Quality Director and all employees who are directly responsible for the release of Covered Products for distribution in the United States shall become Manufacturing Covered Persons. GSK shall have thirty (30) days to determine whether such new facility will continue to release Covered Products for distribution in the United States independently of the Zebulon, North Carolina facility. If, within the thirty (30) day period, GSK decides that such new facility will continue to release Covered Products independently of the Zebulon, North Carolina facility, then such facility shall become a Covered Manufacturing Facility and employees listed in Section II.C.1 of this Appendix shall be Manufacturing Covered Persons. If, within the thirty (30) day period, GSK determines that Covered Products manufactured at the new facility will be released under the supervision of the Zebulon, North Carolina facility, then such new facility shall not become a Covered Manufacturing Facility. In such event, the Site Director, the Site Quality Director and all employees at the facility who are directly responsible for authorizing the release of Covered Products for distribution in the United States shall be Manufacturing Covered Persons. GSK shall notify the OIG about the new Covered Manufacturing Facility in accordance with the timeframes specified in Section IV of the CIA.

## **V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Appendix Implementation Report. Within 150 days after the Effective Date, GSK shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Appendix (Appendix D Implementation Report). The Appendix D Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the GMS Compliance Officer required by Section III.A of this Appendix, and a summary of other noncompliance job responsibilities the GMS Compliance Officer may have;
2. the names and positions of the members of the GMS Compliance Committee required by Section III.A.2 of this Appendix;
3. the names of the members of the Board of Directors referenced in Section III.A.3 of this Appendix;
4. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1 of this Appendix, the percentage of individuals

who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG upon request);

5. a summary of all Policies and Procedures required by Section III.B of this Appendix (copies of the Policies and Procedures shall be made available to OIG upon request);

6. the following information regarding each type of training required by Section III.C of this Appendix:

- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be made available to OIG upon request.

7. A description of GSK's corporate structure as it relates to GMS and cGMP Activities; and

8. the certifications required by Section V.C of this Appendix.

B. Appendix Annual Reports. GSK shall submit to OIG annually a report with respect to the status of, and findings regarding, GMS's compliance activities for each of the five Reporting Periods (Appendix Annual Report).

Each Appendix Annual Report shall include, at a minimum:

1. Any change in the identity, position description, or other noncompliance job responsibilities of the GMS Compliance Officer, any changes in the membership of the GMS Compliance Committee, and any changes in the membership of the Board as described in Section III.A of this Appendix;

2. The Board resolution required by Section III.A.3 of this Appendix;

3. The number of individuals required to complete the Code of Conduct certification required by Section III.B.1 of this Appendix, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG upon request);

4. A summary of any significant changes or amendments to the Policies and Procedures required by Section III.B of this Appendix and the reasons for such changes.

5. The following information regarding each type of training required by Section III.C of this Appendix:

- a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

A copy of all training materials and the documentation to support this information shall be made available to OIG upon request.

6. A copy of any recall notices issued during the Reporting Period by GSK for Covered Products sold in the United States, a description of GSK's corrective action(s) taken related to the recall, and any further steps GSK plans to take related to the recall.

7. A summary of Manufacturing Reportable Events (as defined in Section III.E) identified during the Reporting Period and the status of any corrective action relating to each such Reportable Events;

8. A description of any changes to GSK's corporate structure as reported pursuant to Section V.A.7 of this Appendix D and an identification of any Covered Manufacturing Facility, if any, in lieu of or in addition to the Zebulon facility;

9. The certifications required by Section V.C.

The first Appendix Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Appendix Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Appendix Annual Report.

C. Certifications. The Appendix Implementation Report and each Appendix Annual Report shall include a certification by the GMS Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the report, GMS is in compliance in all material respects with cGMP Requirements and all of the requirements of this CIA; and

2. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful.

D. Designation of Information. GSK shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. GSK shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this Appendix D shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

GSK:

Guy Wingate  
Vice President - GMS Compliance Officer  
GlaxoSmithKline  
GSK House (Mailstop BNG-15)  
980 Great West Road  
Brentford  
Middlesex  
TW8 9GS  
United Kingdom  
Telephone: +44-1833-693330  
Facsimile: +44-2080-476905

Paul Noll  
Vice President - Associate General Counsel  
Legal Operations - Global Manufacturing and Supply  
GlaxoSmithKline  
Five Moore Drive  
Ruvane Building - Mailstop E.3334  
Research Triangle Park, NC 27709  
Telephone: (919) 483-2444  
Facsimile: (919) 483-2881

Unless otherwise specified, all notifications and reports required by this Appendix may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, GSK may be required to provide OIG with an electronic copy of each notification or report required by this Appendix to the CIA in searchable portable document format (pdf), in addition to a paper copy.

## Appendix E to CIA for GlaxoSmithKline LLC

### Executive Financial Recoupment Program

**Executive Financial Recoupment Program.** Through its Existing Commitments and the New Commitments to be implemented, GSK shall establish and maintain throughout the term of the CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay (*i.e.*, annual bonus, plus long term incentives) for an executive who is discovered to have been involved in any significant misconduct (Executive Financial Recoupment Program). This financial recoupment program shall apply to Covered Executives, as defined below in Paragraph B, who are either current GSK employees or who are former GSK employees at the time of a Recoupment Determination.

(A) **Existing Commitments.** The annual cash bonus for each GSK employee based in the United States and the United Kingdom is at risk of forfeiture in the event of employee misconduct that is discovered by GSK before the bonus is paid. In the event of misconduct by any GSK employee worldwide, GSK also has reserved the right and full discretion to void and forfeit any unvested share options and any unvested restricted share grants under the GSK Share Option Plan, Share Value Plan and Performance Share Plan (collectively, the “LTI Plans”). If GSK discovers any employee misconduct that would implicate the forfeitures described in this paragraph, it shall evaluate the situation and make a determination about whether any forfeiture, and the terms of such forfeiture, shall be implemented.

(B) **New Commitments.** In addition to the compensation forfeiture provisions already in place with respect to annual bonuses and the LTI Plans, within 120 days after the Effective Date of the CIA, GSK shall modify and supplement its annual bonus plan and LTI Plan requirements (and any employment agreements, as appropriate) by imposing the following eligibility and repayment conditions on future bonuses and LTI Plan grants, as well as establishing the mandatory deferred annual bonus, tolling remedy, and additional remedies discussed below (collectively, “New Commitments”) to all members of GSK’s Corporate Executive Team (CET) and to any Vice Presidents and Senior Vice Presidents in Grades 0, 1, and 2 who are based in the United States (collectively “Covered Executives”). The New Commitments shall apply prospectively to Covered Executives beginning with the 2013 bonus plan year and LTI Plan grants.

(i) **Executive Bonus Eligibility and Repayment Conditions.** GSK shall implement an eligibility and repayment condition on annual bonuses designed to survive both the payment of the bonus and the separation of a Covered Executive’s employment. This will allow GSK, as a consequence of a Triggering Event as defined below in Paragraph C, to pursue repayment from the Covered Executive of all or any portion of the bonus monies paid to the Covered Executive. To the extent permitted by

controlling law, these bonus eligibility and repayment conditions will survive the payment of the Covered Executive's bonus and the separation of the Covered Executive's employment for a period of 3 years from the payment of the bonus for the plan year.

Consistent with a Recoupment Determination, as defined below in Paragraph D, GSK shall endeavor to collect repayment of any bonus from the Covered Executive through reasonable and appropriate means according to the terms of its bonus plan (or executive contract, as the case may be), and to the extent permitted by controlling law of the relevant jurisdiction. If necessary to collect the repayment, GSK shall file suit against the Covered Executive unless good cause exists not to do so. For purposes of the Executive Financial Recoupment Program, good cause shall include, but not be limited to, a financial inability on the part of the Covered Executive to repay any recoupment amount or GSK's inability to bring such a suit under the controlling law of the relevant jurisdiction.

(ii) **LTI Plans.** Prior to the Effective Date, GSK implemented a recoupment process for Covered Executives' unvested LTI share grants as discussed in Paragraph A (Existing Commitments) above. With respect to current GSK Covered Executives, GSK shall maintain these Existing Commitments and follow the Recoupment process and procedures established by the Recoupment Committee for the duration of the CIA. GSK shall also implement an eligibility and repayment condition on share grants made under LTI Plans designed to survive the separation of a Covered Executive's employment.

To the extent necessary, GSK shall implement an eligibility and repayment condition on grants made under the LTI Plans in order to clarify that, as a consequence of a Triggering Event, GSK may pursue repayment by a Covered Executive who is a former employee of all or any portion of the last 3 years' worth of share option and restricted share grants that became vested and were paid during the Covered Executive's last years of employment and following termination of employment.

To the extent permitted by controlling law, these eligibility and repayment conditions shall survive vesting and payment for a period of 3 years from the Covered Executive's employment termination date. In addition, GSK shall amend the vesting schedule in the LTI Plans so that Covered Executives who are "good leavers" (e.g., terminating employment due to retirement, death or disability) will no longer vest in, nor receive a distribution of, any unvested share options or restricted shares immediately following termination of employment; rather, these LTI Plan grants will only vest and be distributable after the first anniversary of the Covered Executive's termination of employment. Consistent with a Recoupment Determination, GSK shall endeavor to collect repayment of these LTI Plan awards from the Covered Executive through reasonable and appropriate means and to the extent permitted by controlling law of the jurisdiction in which the Covered Executive works. If necessary to collect the

repayment, GSK shall file suit against the Covered Executive unless good cause exists not to do so.

(iii) **Mandatory Deferred Annual Bonus.** GSK shall establish a deferred compensation plan that requires the deferral of ten (10%) percent of a Covered Executive's annual bonus (twenty-five (25%) percent, in the case of CET members) for a 3-year period that survives separation of the Covered Executive's employment. Bonuses deferred under the plan shall be matched on a dollar-for-dollar basis by GSK. Consistent with a Recoupment Determination, all deferred bonuses, matching contributions and any related gains thereon are subject to forfeiture and voidance as a consequence of a Triggering Event.

(iv) **Tolling Remedy.** To the extent permitting by controlling law, for the 3 years during which the bonus eligibility and repayment conditions exist, if GSK reasonably anticipates that a Triggering Event has occurred pursuant to Paragraph C, and GSK has recoupment rights remaining under Paragraphs B(i) and B(ii), GSK shall have the right to notify the Covered Executive that those rights shall be tolled and thereby extended for an additional 3 years or until the Recoupment Committee determines that a Triggering Event has not occurred, whichever is earlier, to the extent permitted by controlling law of the relevant jurisdiction.

(v) **Additional Remedies.** If, after expiration of the time period specified in Paragraphs B(i)-(iii) above, the Recoupment Committee determines that a Triggering Event occurred, GSK shall make a determination as to whether to pursue available remedies (*e.g.*, filing suit against the Covered Executive) existing under statute or common law to the extent available.

(C) **Definition of Triggering Events.** The eligibility and repayment conditions described above shall be triggered upon a Recoupment Determination that finds:

(i) significant misconduct (*e.g.*, violation of a significant GSK policy, or regulation, or law) by the Covered Executive that, if discovered prior to payment, would have made the Covered Executive ineligible for an annual bonus, bonus deferral or LTI Plan grant in that plan year or subsequent plan years; or

(ii) significant misconduct by subordinate employees in the business unit over which the Covered Executive had responsibility that does not constitute an isolated occurrence and which the Covered Executive knew or should have known was occurring that, if discovered prior to payment, would have made the Covered Executive and/or employees in question ineligible for an annual bonus, bonus deferral or LTI Plan grant in that plan year or subsequent plan years.

(D) **Administration of Recoupment Program.** GSK shall engage in a standardized, formal process to determine, in its sole discretion, whether a Triggering Event has occurred, and, if so, the extent of bonus monies, LTI Plan grants and deferred compensation that will be subject to repayment or forfeiture by the Covered Executive, and the most appropriate method for securing recoupment of relevant monies previously paid to a Covered Executive. The findings and conclusions resulting from this process shall be referred to as the “Recoupment Determination”.

(i) **Initiation.** GSK shall initiate the Recoupment Determination process upon: (1) discovery of potential significant misconduct that may rise to the level of a Triggering Event, or (2) written notification by a United States federal government agency to the Senior Vice President for Governance, Ethics, and Assurance of GlaxoSmithKline PLC of a situation that may rise to the level of a Triggering Event and either occurred in the United States or gives rise to liability relating to Federal healthcare programs. This written notification shall either identify the Covered Executive(s) potentially at issue or provide information (*e.g.*, a description of the alleged misconduct and the applicable time period) to allow GSK to identify the Covered Executive.

(ii) **Recoupment Committee.** The Recoupment Determination shall be made by a committee of senior executives headed by the Senior Vice President for Governance, Ethics, and Assurance of GlaxoSmithKline PLC (Recoupment Committee). With respect to members of the CET, a Recoupment Determination shall be subject to ratification by the Board of Directors (or appropriate committee thereof) of GlaxoSmithKline PLC.

(iii) **Timeline for Recoupment Determination Process.** GSK shall initiate the Recoupment Determination process within 30 days after discovery by GSK or notification, pursuant to Paragraph D(i), of a potential Triggering Event. Absent extraordinary reasons, GSK shall reach a Recoupment Determination within 90 days after initiation of the determination process.

In connection with making its Recoupment Determination, the Recoupment Committee or appropriate Delegate pursuant to implementing policies and procedures shall: i) undertake an appropriate and substantive review or investigation of the facts and circumstances associated with the Triggering Event or any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; ii) make written findings regarding the facts and circumstances associated with the Triggering Event and any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; and iii) set forth in writing its determinations (and the rationale for such determinations) about: 1) whether a Triggering Event occurred; 2) the extent of

bonus monies, LTI Plan grants or deferred compensation that will be subject to forfeiture and/or repayment by the Covered Executive; 3) the means that will be followed to implement the forfeiture and/or secure the recoupment of performance pay from the Covered Executive; and 4) the timetables under which GSK will implement the forfeiture and/or attempt to recoup the performance pay. For purposes of this paragraph, a “Delegate” shall refer to the GSK personnel to whom the Recoupment Committee has delegated one or more of its required tasks in furtherance of the Executive Financial Recoupment Program.

(E) **Reporting.** The Recoupment Committee shall provide annual reports to the Board of Directors (or an appropriate committee thereof) of GlaxoSmithKline PLC about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; ii) a description of any Recoupment Determinations made during the preceding year (including any decision to require or not require forfeiture/recoupment from any Covered Executives, the amount and type of any forfeiture/recoupment, the means for collecting any recoupment and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Recoupment Determinations that were not fully completed in prior years.

The Recoupment Committee shall also provide annual reports to the OIG about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; ii) a summary description of any Recoupment Determinations made during the preceding year (including any decision to require or not require forfeiture/recoupment from any Covered Executives, the amount and type of any forfeiture/recoupment, the method for collecting any recoupment, and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Recoupment Determinations that were not fully completed in prior years.

GSK commits to maintaining all of the forfeiture and recoupment commitments set forth in Paragraphs A-E above for at least the duration of the CIA, absent agreement otherwise with the OIG.



# GSK China Investigation Outcome

## 19 September 2014

GlaxoSmithKline plc (GSK) today announced that the Changsha Intermediate People's Court in Hunan Province, China ruled that GSK China Investment Co. Ltd (GSKCI) has, according to Chinese law, offered money or property to non-government personnel in order to obtain improper commercial gains, and been found guilty of bribing non-government personnel. The verdict follows investigations initiated by China's Ministry of Public Security in June 2013.

As a result of the Court's verdict, GSKCI will pay a fine of £297 million (3 billion RMB at a currency exchange rate of 10.0980) to the Chinese government. This will be funded through existing cash resources. Associated costs and charges related to restructuring will be included in GSK's third quarter update.

The illegal activities of GSKCI are a clear breach of GSK's governance and compliance procedures; and are wholly contrary to the values and standards expected from GSK employees. GSK has published a statement of apology to the Chinese government and its people on its website ([www.gsk-china.com](http://www.gsk-china.com)).

GSK has co-operated fully with the authorities and has taken steps to comprehensively rectify the issues identified at the operations of GSKCI. This includes fundamentally changing the incentive program for its salesforces (decoupling sales targets from compensation); significantly reducing and changing engagement activities with healthcare professionals; and expanding processes for review and monitoring of invoicing and payments.

GSK Chief Executive Officer, Sir Andrew Witty said: "Reaching a conclusion in the investigation of our Chinese business is important, but this has been a deeply disappointing matter for GSK. We have and will continue to learn from this. GSK has been in China for close to a hundred years and we remain fully committed to the country and its people. We will continue to expand access to innovative medicines and vaccines to improve their health and well-being. We will also continue to invest directly in the country to support the government's health care reform agenda and long-term plans for economic growth."

Exhibit

6

GSK – one of the world’s leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit [www.gsk.com](http://www.gsk.com).

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**ADMINISTRATIVE PROCEEDING**  
**File No. 3-17606**

**GlaxoSmithKline Pays \$20 Million Penalty to Settle FCPA Violations**

**September 30, 2016** – The Securities and Exchange Commission today announced that GlaxoSmithKline plc (“GSK”) has agreed to pay \$20 million to settle charges that it violated the Foreign Corrupt Practices Act (FCPA) when its China-based subsidiaries engaged in pay-to-prescribe schemes to increase sales.

An SEC investigation found that the schemes spanned a period of years and involved the transfer of money, gifts, and other things of value to health care professionals, which led to millions of dollars in increased sales of GSK pharmaceutical products to China’s state health institutions. The participants included certain complicit sales and marketing managers within GSK’s China-based subsidiaries. GSK failed to devise and maintain a sufficient system of internal accounting controls and lacked an effective anti-corruption compliance program to detect and prevent these schemes. As a result, the improper payments were not accurately reflected in GSK’s books and records.

The SEC’s order finds that GSK violated the FCPA’s internal controls and books-and-records provisions. GSK consented to the order without admitting or denying the findings, and agreed to pay a \$20 million civil penalty. GSK also agreed to provide status reports to the SEC for the next two years on its remediation and implementation of anti-corruption compliance measures.

**See also:**     [Order](#)

# # #

**UNITED STATES OF AMERICA**  
**Before the**  
**SECURITIES AND EXCHANGE COMMISSION**

**SECURITIES EXCHANGE ACT OF 1934**  
**Release No. 79005 / September 30, 2016**

**ACCOUNTING AND AUDITING ENFORCEMENT**  
**Release No. 3810 / September 30, 2016**

**ADMINISTRATIVE PROCEEDING**  
**File No. 3-17606**

**In the Matter of**

**GlaxoSmithKline plc,**

**Respondent.**

**ORDER INSTITUTING CEASE-AND-DESIST  
PROCEEDINGS, PURSUANT TO SECTION  
21C OF THE SECURITIES EXCHANGE ACT  
OF 1934, MAKING FINDINGS, AND  
IMPOSING REMEDIAL SANCTIONS AND A  
CEASE-AND-DESIST ORDER**

**I.**

The Securities and Exchange Commission (“Commission”) deems it appropriate that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 21C of the Securities Exchange Act of 1934 (“Exchange Act”), against GlaxoSmithKline plc (“Respondent”).

**II.**

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the “Offer”) which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission’s jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings, Pursuant to 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing Remedial Sanctions and a Cease-and-Desist Order (“Order”), as set forth below.

### III.

On the basis of this Order and Respondent's Offer, the Commission finds<sup>1</sup> that

#### **Summary**

A. These proceedings arise out of GSK's violations of the internal controls and recordkeeping provisions of the Foreign Corrupt Practices Act of 1977 (the "FCPA") [15 U.S.C. § 78dd].

B. Between at least 2010 and June 2013, employees and agents of GSK's China-based subsidiary and a China-based joint-venture engaged in various transactions and schemes to provide things of value to foreign officials, including healthcare professionals ("HCPs"), in order to improperly influence them and increase sales of GSK products in China.

C. This misconduct was facilitated in part by the use of collusive third parties that ostensibly provided legitimate travel and other services. The funds used for the improper inducements were frequently obtained under the guise of, and falsely recorded in GSK's books and records as, legitimate travel and entertainment expense, marketing expense, speaker payments, medical associations payments, and promotion expense. Throughout this period GSK failed to devise and maintain a sufficient system of internal accounting controls and lacked an effective anti-corruption compliance program.

D. The deficiencies in GSK's internal accounting controls and compliance program also led to instances of similar improper conduct in connection with sales in other countries in which GSK operates.

#### **Respondent**

E. GlaxoSmithKline plc is a corporation organized in the United Kingdom. Its headquarters are located in Middlesex, United Kingdom. GSK's common stock is registered with the Commission under Section 12(b) of the Securities Exchange Act and trades on the New York Stock Exchange under the symbol 'GSK'.

F. GSK is a global provider of pharmaceutical and consumer health care products and its products are sold in at least 150 countries.

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<sup>1</sup> The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

### **Other Relevant Entities**

G. **GlaxoSmithKline (China) Investment Co Ltd** (“GSKCI”) is operated from Shanghai, China. GSKCI operations include the sale and marketing of pharmaceutical products. GSKCI is a wholly-owned indirect subsidiary of GSK.

H. **Sino-American Tianjin Smith Kline & French Laboratories Ltd** (“TSKF”) is a public-private joint venture with Tianjin Zhong Xin Pharmaceutical Group Corporation Ltd and Tianjin Pharmaceutical Group Co Ltd. GSK indirectly owns 55 percent of TSKF.

### **Facts**

I. From at least 2010 to June 2013, employees and agents of GSKCI and TSKF engaged in transactions and schemes to corruptly transfer things of value to foreign officials in China to increase sales of pharmaceutical products. The payments were made to increase sales through increased prescriptions by individual HCPs and purchases by hospital administrative staff responsible for product selection or purchase. The conduct occurred across all geographic areas within the sales and marketing functions and impacted all product lines.

J. The corrupt payments took varied forms, including gifts, improper travel and entertainment with no or little educational purpose, shopping excursions, family and home visits, and cash. The costs associated with these payments were recorded in GSK’s books and records as legitimate expenses, such as medical association sponsorships, employee expenses, conferences, speaker fees, and marketing costs.

K. These improper practices were pervasive among GSKCI’s and TSKF’s sales and marketing representatives and were condoned by regional and district managers. For example, a 2013 work plan submitted by a sales representative to a regional sales manager described the intent to pay, among other things, an HCP RMB 20/box of prescribed product every month, and deliver appropriate gifts on each holiday in exchange for a guarantee of more than 40 boxes of prescribed product every month.

L. Among the ways employees were able to fund payments to HCPs was the use of collusive third party vendors, such as those used to perform planning and travel services for events involving HCPs. Between 2010 and June 2013, GSKCI spent nearly RMB 1.4 billion (USD \$225 million) on planning and travel services. Test sampling showed that approximately 44 percent of the sampled invoices were inflated and approximately 12 percent were for events that did not occur.

M. Controls weaknesses also permitted ostensibly legitimate speaker fees to be used to improperly influence HCPs. While GSK’s policies as of 2010 placed limits on the amount of fees paid to speakers per hour and by 2012 cumulatively per year, there was no effective system in place to ensure the actual identity of a speaker. Of approximately RMB 106 million (USD \$17 million) spent by GSKI in speaker fees, approximately RMB 14 million (USD \$2.2 million) was paid to persons whose qualification as an HCP could not be verified.

N. Marketing programs were another mechanism used to improperly influence HCPs. For example, in 2010, GSKCI engaged a local vendor to facilitate a national marketing program called the Cold Chain Project. The project was intended to provide healthcare clinics with tools to facilitate the storage and administration of vaccines that required refrigeration. However, the project was instead used to provide HCPs with gifts such as laptops, tablets, and other electronic devices. Over the life of the project, GSKCI paid out RMB 14.6 million (approximately USD \$2.3 million). The project was created and administered by senior marketing and sales managers of GSKCI. The clinics selected were based upon the potential to market additional pharmaceutical products.

O. During this period, local internal audit and compliance reviews identified controls deficiencies and evidence of some mechanisms that were used to fund the improper payments, but they were treated as isolated instances rather than signs of a larger problem. For example, in 2013 a Sales Rep Office Audit was conducted by internal audit with respect to the Guangzhou office. Among the problems identified were:

- Issues of falsified POS slips and fake bank statements
- Issues of fake invoices claimed from hotels and restaurants for sales meeting activities. These invoices came from a local preferred meeting agency used by the Guangzhou office.
- Compliance and New Employee training not timely completed
- Sales employees' salaries were significantly driven by commissions that could lead to an incentive to improperly inflate sales. The audit sampled 20 percent of the sales team for the office and found that for 41 percent their sales commission bonuses were greater than 50 percent of their income.

P. As early as 2010, internal audit identified problems related to sales and promotions staff practices in China. Among other findings it noted:

[d]uring 2010, several new policies governing commercial activities such as grants and donations and sponsorships were introduced. The significant changes, combined with the high staff turnover, contribute to an environment where many commercial and medical staff do not understand how to apply policies or the rationale behind them. This was evidenced by approval of non-compliant activities, a lack of clarity on which policy to apply for activities such as grants, and weaknesses in documentation to support the legitimate intent of activities such as advisory boards and sponsorships of HCPs to attend meetings.

Q. As a result of the conduct described above, Respondent violated Sections 13(b)(2)(A) and 13(b)(2)(B) of the Securities Exchange Act of 1934 [15 U.S.C. §§ 78m(b)(2)(A) and 78m(b)(2)(B)].

### **GSK's Remedial Efforts**

R. In determining to accept the Offer, the Commission considered remedial acts promptly undertaken by Respondent and cooperation afforded the Commission staff.

1. During the course of the investigation, Respondent provided prompt and regular briefings regarding its own internal investigation in China, and with respect to other countries. Respondent timely conveyed the facts it learned in the course of its own investigation, promptly responded to document requests by the Commission staff, and provided translations of documents as needed.
2. Respondent also provided detailed and timely information regarding its remedial efforts, enhancements to its compliance program and implementation of key initiatives.
3. Respondent made global changes to its business. This included the elimination of most payments to doctors, including fees to HCPs to speak about the Company's prescription medicines, and altering the compensation structure for its sales force to eliminate incentive pay based on the number of prescriptions generated. Respondent enhanced its global risk assessment process, strengthened its monitoring and risk assessment tools, and increased its global compliance organization. Respondent also enhanced its third-party oversight program, including increasing the number and scope of third-party audits, and increased training and education of employees on anti-bribery issues.

### **Undertakings**

S. Respondent has undertaken to:

1. Report to the Commission staff periodically, at no less than nine-month intervals during a two-year term, the status of its remediation and implementation of compliance measures. During this two-year period, should Respondent discover credible evidence, not already reported to the Commission staff, that questionable or corrupt payments or questionable or corrupt transfers of value may have been offered, promised, paid, or authorized by Respondent, or any entity or person acting on behalf of Respondent, or that related false books and records have been maintained, Respondent shall promptly report such conduct to the Commission staff. During this two-year period, Respondent shall: (a) conduct an initial review and submit an initial report, and (b) conduct and prepare at least two follow-up reviews and reports, as described below:
  - i. Respondent shall submit to the Commission staff a written report within 180 calendar days of the entry of this Order setting forth a complete description of its Foreign Corrupt Practices Act ("FCPA") and anti-corruption related remediation efforts to

date, its proposals reasonably designed to improve the policies and procedures of Respondent for ensuring compliance with the FCPA and other applicable anticorruption laws, and the parameters of the subsequent reviews (the “Initial Report”). The Initial Report shall be transmitted to Charles Cain, Deputy Unit Chief, FCPA Unit, Division of Enforcement, United States Securities and Exchange Commission, 100 F St NE, Washington, DC 20549. Respondent may extend the time period for issuance of the Initial Report with prior written approval of the Commission staff.

- ii. Respondent shall undertake at least two follow-up reviews, incorporating any comments provided by the Commission staff on the previous report, to further monitor and assess whether the policies and procedures of Respondent are reasonably designed to detect and prevent violations of the FCPA and other applicable anti-corruption laws (the “Follow-up Reports”).
  - iii. The first Follow-up Report shall be completed by no later than 270 days after the Initial Report. The second Follow-up Report shall be completed by no later than 450 days after the completion of the Initial Report. Respondent may extend the time period for issuance of the Follow-up Reports with prior written approval of the Commission staff.
  - iv. The periodic reviews and reports submitted by Respondent will likely include proprietary, financial, confidential, and competitive business information. Public disclosure of the reports could discourage cooperation, impede pending or potential government investigations and thus undermine the objectives of the reporting requirement. For these reasons, among others, the reports and the contents thereof are intended to remain and shall remain non-public, except (a) pursuant to court order, (b) as agreed by the parties in writing, (c) to the extent that the Commission staff determines in its sole discretion that disclosure would be in furtherance of the Commission’s discharge of its duties and responsibilities, or (d) is otherwise required by law.
2. Certify, in writing, compliance with the undertaking(s) set forth above. The certification shall identify the undertaking(s), provide written evidence of compliance in the form of a narrative, and be supported by exhibits sufficient to demonstrate compliance. The Commission staff may make reasonable requests for further evidence of compliance, and Respondent agrees to provide such

evidence. The certification and supporting materials shall be submitted to Charles Cain, Deputy Unit Chief, FCPA Unit, with a copy to the Office of the Chief Counsel of the Enforcement Division, no later than sixty (60) days from the date of the completion of the undertakings.

#### IV.

In view of the foregoing, the Commission deems it appropriate to impose the sanctions agreed to in Respondent's Offer. Accordingly, pursuant to Section 21C of the Exchange Act, it is hereby ORDERED that:

A. Respondent cease and desist from committing or causing any violations and any future violations of Sections 13(b)(2)(A) and 13(b)(2)(B) of the Securities Exchange Act of 1934 [15 U.S.C. §§ 78m(b)(2)(A) and 78m(b)(2)(B)].

B. Respondent shall, within 10 days of the entry of this Order, pay a civil money penalty in the amount of \$20,000,000 to the Securities and Exchange Commission for transfer to the general fund of the United States Treasury, subject to Exchange Act Section 21F(g)(3). If timely payment is not made, additional interest shall accrue pursuant to 31 U.S.C. §3717. Payment must be made in one of the following ways:

- (1) Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;
- (2) Respondent may make direct payment from a bank account via Pay.gov through the SEC website at <http://www.sec.gov/about/offices/ofm.htm>; or
- (3) Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center  
Accounts Receivable Branch  
HQ Bldg., Room 181, AMZ-341  
6500 South MacArthur Boulevard  
Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying GSK as a Respondent in these proceedings, and the file number of these proceedings; a copy of the cover letter and check or money order must be sent to Charles Cain, Division of Enforcement, Securities and Exchange Commission, 100 F St., NE, Mailstop 5631, Washington, DC 20549.

C. Amounts ordered to be paid as civil money penalties pursuant to this Order shall be treated as penalties paid to the government for all purposes, including all tax purposes. To preserve the deterrent effect of the civil penalty, Respondent agrees that in any Related Investor

Action, it shall not argue that it is entitled to, nor shall it benefit by, offset or reduction of any award of compensatory damages by the amount of any part of Respondent's payment of a civil penalty in this action ("Penalty Offset"). If the court in any Related Investor Action grants such a Penalty Offset, Respondent agrees that it shall, within 30 days after entry of a final order granting the Penalty Offset, notify the Commission's counsel in this action and pay the amount of the Penalty Offset to the Securities and Exchange Commission. Such a payment shall not be deemed an additional civil penalty and shall not be deemed to change the amount of the civil penalty imposed in this proceeding. For purposes of this paragraph, a "Related Investor Action" means a private damages action brought against Respondent by or on behalf of one or more investors based on substantially the same facts as alleged in the Order instituted by the Commission in this proceeding.

D. Respondent shall comply with the undertakings enumerated in Section III above.

By the Commission.

Brent J. Fields  
Secretary

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PETER HUMPHREY,  
YU YINGZENG  
CHINAWHYS COMPANY LTD

Plaintiffs,

V,

GLAXOSMITHKLINE PLC;  
GLAXOSMITHKLINE LLC

Defendants.

Case No. 2:16 cv 5924

**DECLARATION OF GSK CHINA (INVESTMENT) CO. LTD.**

I, Thomas Willemsen, being above 18 years of age and competent to make this declaration, hereby declare that:

1. My name is Thomas Willemsen. I am aware and cognizant of the facts set forth in this Declaration and am able to swear, and I hereby do swear, that all of the matters contained in this Declaration are true and correct.

2. I am currently employed as VP and General Manager, China Pharmaceuticals and Vaccines, for GlaxoSmithKline (China) Investment Co. Ltd. ("GSK China").

3. GSK China is a wholly-owned indirect subsidiary of GlaxoSmithKline plc ("GSK PLC"), and it is incorporated under Chinese law.

4. GSK China and GSK PLC maintain all the formalities of separate corporations. GSK China maintains books and records, payrolls, bank accounts, and a board of directors

independently of GSK PLC. GSK China and GSK PLC are separately and adequately capitalized.

5. GSK China's principal place of business is in Shanghai, China.

6. GSK China has never conducted commercial operations in the United States or the Commonwealth of Pennsylvania.

7. GSK China was the GSK entity which executed the Consultancy Agreement entered into between GSK China and ChinaWhys, through the ChinaWhys alter egos ChinaWhys (Shanghai) Consulting Co. Ltd. and ChinaWhys Co. Ltd., which is the subject of the within litigation. No other GSK entity was a party to the Consultancy Agreement.

8. From April through July of 2013, the below-referenced GSK-affiliated individuals named in the above referenced complaint ("Complaint") were employed by GSK China, based in China, and performed services that were directed towards China:

- a. Mark Reilly;
- b. April Zhao;
- c. Leslie Chang; and
- d. Maggie Zheng.

9. From April through July of 2013, Jennifer Huang was employed by GlaxoSmithKline (China) R&D Company Limited, based in China, and performed services that were directed towards China.

10. From April through July 2013, Brian Cahill ("Cahill") was an employee of GlaxoSmithKline Pte. Ltd., was based in Singapore, and was employed as Senior Vice President and General Counsel, Asia. During April through July 2013, Cahill had oversight over GSK China's legal operations, among other responsibilities.

11. From April through July 2013, June Soon was an employee of GlaxoSmithKline

Pte. Ltd., was based in Singapore, and was employed as an executive secretary supporting Cahill.

12. On July 2, 2012, GSK LLC agreed to plead guilty and to pay \$3 billion to resolve criminal and civil liabilities arising from the promotion of certain prescription drugs, the failure to report certain safety data, and its civil liabilities for alleged false price reporting practices, arising from various conduct that occurred in the United States between 1994 - 2010 ("2012 U.S. Settlement"). GSK China was not a party to the 2012 U.S. Settlement.

13. On September 19, 2014, the Changsha Intermediate People's Court in Hunan Province, China entered a judgment against GSK China for approximately \$489.5 million in connection with violations by GSK China personnel of Chinese law prohibiting bribery of non-governmental Chinese personnel ("2014 China Judgment"). None of the conduct that was the subject of the 2014 China Judgment occurred in the United States. Neither GSK PLC nor GSK LLC were parties to the 2014 China Judgment.

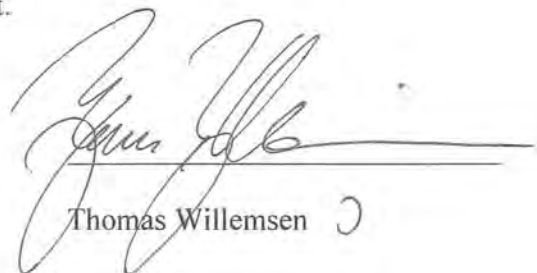
14. On September 30, 2016, the United States Securities and Exchange Commission ("U.S. SEC") and GSK PLC entered into a civil resolution concerning internal controls and recordkeeping provisions of the United States Foreign Corrupt Practices Act of 1977 relating to conduct in China involving GSK China and a related joint-venture ("2016 U.S. Settlement"). GSK China was not a party to the 2016 U.S. Settlement.

\* \* \*

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

DATE:

Jan 16, 2017



Thomas Willemssen



# ChinaWhys

|| About Us ||

## An International Business Risk Advisory Firm with Eyes in China

As the global supply chain undergoes a quantum shift, with multinational corporations relocating their supply base to Asia and increasingly to China, with global sourcing operations centering on this region, the risks and challenges can sometimes be as great as and sometimes greater than the rewards and profits. ChinaWhys is there to help you avoid the landmines.

Outsourcing, localization and technology transfer are irresistible trends that go hand in hand with the supply chain shift, bringing efficiencies, economies, competitiveness, enhanced profitability, but also the new and hidden dangers of an unknown landscape.

We are international business advisors with eyes in China, walking multinationals through the labyrinth of opportunity, risk and unfamiliar cultural environment.

ChinaWhys is a professional-services consultancy that specializes in discreet risk mitigation solutions, consulting and investigation services to corporate clients in matters of high sensitivity across Greater China and the Asia Pacific. Incorporated in Hong Kong, ChinaWhys has an extensive and discreet network of resources across China and the region, and has associates in all regions of the world.

ChinaWhys was founded in 2003 by Peter Humphrey, who has spent more than 30 years dealing with China and Eastern Europe. He has set the standard for the risk mitigation industry in China through his service to multinationals during China's recent opening-up to world business.

We have provided regular advice to the business community on risk management and conducted services in China for large, medium and small multinationals, professional services firms, NGOs, chambers of commerce and high wealth individuals.

We are a cost-effective practice with an extensive network of contacts with regulatory agencies, investigators, international and local law firms, and professionals across the country that enables us to conduct wide ranging discreet inquiries into difficult commercial matters ranging from pre-transactional issues, and fraud and employee corruption, to intellectual property abuse and other business crises. We have experience in serving a wide spectrum of industries from manufacturing and logistics to law practices and accounting firms.

[Click here to understand the Reality of Business Risk and our Objectives.](#)



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# ChinaWhys

|| About Us ||

## Peter Humphrey

### Managing Director of ChinaWhys

Peter is the founder of ChinaWhys, a risk management consultancy that provides creative approaches to critical business problems in China. ChinaWhys offers discreet risk mitigation solutions, consulting and commercial investigation services to corporate clients in important and sensitive matters across the Greater China region and beyond.

Peter has spent 37 years involved with China and Eastern European countries. After two decades as a foreign correspondent with Reuters in Asia, Eastern Europe and the Balkans, he has spent the past 14 years as a risk management specialist and corporate detective focused on white-collar crime prevention, fraud investigation and crisis mitigation for multinationals in Asia.

Before founding ChinaWhys, Peter had served as China country manager for US risk consultancy Kroll and head of China investigations at PwC as well as undertaking a number of humanitarian assignments.

Peter has a thorough knowledge of the China operating environment and is an authority on fraud and supply chain risks. He resolves critical problems for Fortune 500 companies and works closely with leading international law firms. His successes include neutralizing a counterfeit-and-fraud syndicate that hijacked the business of a global consumer goods manufacturer, eliminating fraud from the buying operation of a leading megastore chain, uncovering fraudulent JV deals for a global appliances manufacturer, and orchestrating the recovery of a kidnapped child in China.

He holds an Honours degree in Oriental Studies from Durham University England and was a fellow of Harvard University 1994-1996. He is fluent in spoken Mandarin and reads and writes Chinese and other foreign languages. He is Founding President of the Shanghai Chapter of the Association of Certified Fraud Examiners (ACFE) and a member of the American Society for Industrial Security (ASIS). He is also active in community service and charity work for underprivileged communities, and served as President of the Rotary Club of Beijing in 2010-2011.

ChinaWhys  
PEOPLE

Peter  
Humphrey

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# ChinaWhys

|| About Us ||

## Yingzeng Yu

### General Manager of ChinaWhys

Yingzeng, ("Ying") is a founder and director of ChinaWhys, a risk management and supply chain services consultancy that provides creative approaches to critical business problems in China. ChinaWhys offers discreet risk mitigation solutions, internal process audits, due diligence and commercial investigation services to corporate clients in matters of great importance and sensitivity across the Greater China region and beyond.

Ying has been in business for more than 25 years during which time she has served as a financial controller in the US and Hong Kong, and as a high-level advisory consultant in China. She has performed extensive financial planning work, advised multinational corporations setting up manufacturing operations in China and conducted financial feasibility studies for foreign venture capital investments. Her industry experience covers computer, telecom components, integrated circuits, PCB, optical system, special materials, chemicals, medical products, food processing, beverages, auto components, wholesale, retail and professional services. As a corporate strategy consultant, Ying has also advised clients on competitive strategy and China market development.

Ying has hands-on experience in all aspects of operational process and is experienced in operational/financial audit to identify management control weakness, FCPA-style bribery concerns and fraud risks. She has worked on numerous pre-transactional due diligence projects and on complex fraud investigations at multinational operations in China. Her successes have included solving a supply chain fraud by establishing activity links to capture criminal evidence for a U.S. food manufacturer, and pinpointing weak HR policies as a threat to effective control for a European retailer. She also led a large-scale investigation into bribery and kickbacks at one of the world's top PC manufacturers, in which her evidence led to top-level dismissals and a thorough reorganisation.

Ying is a Certified Fraud Examiner (CFE) and holds an MBA from the John Anderson Graduate School of Management of the University of California Los Angeles (UCLA) as well as a Bachelor of Science from the School of Business of San Jose State University. She has served as Chairperson of the Transportation and Logistics Forum of the American Chamber of Commerce in China.

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ChinaWhys  
PEOPLE

Yingzeng  
Yu

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PETER HUMPHREY,  
YU YINGZENG  
CHINAWHYS COMPANY LTD

Plaintiffs,

V,

GLAXOSMITHKLINE PLC;  
GLAXOSMITHKLINE LLC

Defendants.

Case No. 2:16 cv 5924

**DECLARATION OF GLAXOSMITHKLINE PLC**

I, Simon Dingemans, being above 18 years of age and competent to make this declaration, hereby declare that:

1. My name is Simon Dingemans. I am aware and cognizant of the facts set forth in this Declaration and am able to swear, and I hereby do swear, that all of the matters contained in this Declaration are true and correct.

2. I am a Director of GlaxoSmithKline plc ("GSK PLC") and am currently appointed as the Chief Financial Officer of GSK PLC.

3. GSK PLC is a public limited company organized under the laws of England and Wales, with its principal place of business at 980 Great West Road, Brentford, Middlesex TW8 9GS, England. GSK PLC is not incorporated under the laws of the Commonwealth of Pennsylvania.

4. GSK PLC is a holding company only. GSK PLC was created and exists solely for the purpose of holding the stock of its subsidiaries, through several layers of wholly owned subsidiaries.

5. GSK PLC has never conducted commercial operations anywhere in the world, including the United States and the Commonwealth of Pennsylvania.

6. GSK PLC has never designed, developed, manufactured, marketed or sold any products or services anywhere in the world, including the United States and the Commonwealth of Pennsylvania.

7. GSK PLC is not and has never been a direct shareholder of GlaxoSmithKline LLC ("GSK LLC").

8. GSK PLC and GSK LLC maintain all the formalities of separate corporations. GSK PLC and GSK LLC do not maintain common books and records, payrolls, bank accounts, or boards of directors. GSK LLC and GSK PLC are separately and adequately capitalized.

9. GSK PLC and GSK China maintain all the formalities of separate corporations. GSK PLC and GSK China do not maintain common books and records, payrolls, bank accounts, or boards of directors. GSK PLC and GSK China are separately and adequately capitalized.

10. GSK PLC does not have operational headquarters in either Philadelphia, Pennsylvania or Research Triangle Park, North Carolina.

11. GSK PLC has never been licensed to do business in Pennsylvania.

12. GSK PLC has never been required to maintain, and has never maintained, a registered agent for service of process in Pennsylvania.

13. GSK PLC has no agents or employees in Pennsylvania.

14. GSK PLC owns no property, real or personal, in the Commonwealth of

Pennsylvania.

15. At least since 2013, GSK PLC has not acquired, disposed of, owned or leased any real property in Pennsylvania.

16. GSK PLC has never filed or been required to file a tax return within the commonwealth of Pennsylvania.

17. GSK PLC was not a party to the April 25, 2013 Consultancy Agreement, including all appendices, entered into between GSK China (Investment) Co. Ltd. ("GSK China") and ChinaWhys, through the ChinaWhys alter egos ChinaWhys (Shanghai) Consulting Co. Ltd. and ChinaWhys Co. Ltd., which is the subject of the within litigation.

18. None of the GSK-affiliated individuals who are referred to in the complaint that was filed in connection with this litigation ("Complaint") were employed by GSK PLC during the relevant time period (April through July 2013) set forth in the allegations:

- a. Mark Reilly;
- b. April Zhao;
- c. Jennifer Huang;
- d. Leslie Chang;
- e. Brian Cahill;
- f. June Soon; and
- g. Maggie Zheng.

19. On July 2, 2012, GSK LLC agreed to plead guilty and to pay \$3 billion to resolve criminal and civil liabilities arising from the promotion of certain prescription drugs, the failure to report certain safety data, and its civil liabilities for alleged false price reporting practices, arising from various conduct that occurred in the United States between 1994 - 2010 ("2012 U.S.

Settlement"). GSK PLC was not a party to the 2012 U.S. Settlement.

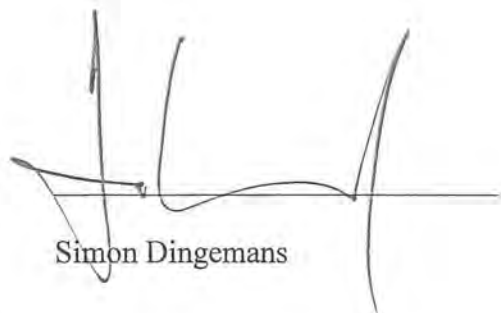
20. On September 19, 2014, the Changsha Intermediate People's Court in Hunan Province, China entered a judgment against GSK China for approximately \$489.5 million in connection with violations by GSK China personnel of Chinese law prohibiting bribery of non-governmental Chinese personnel ("2014 China Judgment"). GSK PLC was not a party to the 2014 China Judgment.

21. On September 30, 2016, the United States Securities and Exchange Commission ("U.S. SEC") and GSK PLC entered into a civil resolution concerning internal controls and recordkeeping provisions of the United States Foreign Corrupt Practices Act of 1977 relating to conduct in China by GSK China and a related joint-venture ("2016 U.S. Settlement"). Neither GSK LLC nor GSK China were parties to the 2016 U.S. Settlement.

\* \* \*

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

DATE: 13<sup>th</sup> January 2017



Simon Dingemans

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PETER HUMPHREY,  
YU YINGZENG  
CHINAWHYS COMPANY LTD

Plaintiffs,

V,

GLAXOSMITHKLINE PLC;  
GLAXOSMITHKLINE LLC

Defendants.

Case No. 2:16 cv 5924

**DECLARATION OF GLAXOSMITHKLINE LLC**

I, William Mosher, being above 18 years of age and competent to make this declaration, hereby declare that:

1. My name is William Mosher. I am aware and cognizant of the facts set forth in this Declaration and am able to swear, and I hereby do swear, that all of the matters contained in this Declaration are true and correct.
2. I am currently employed as Vice President & Associate General Counsel of GlaxoSmithKline LLC ("GSK LLC").
3. GSK LLC is a limited liability company organized in the state of Delaware, with corporate operations in Research Triangle Park, North Carolina and Philadelphia, Pennsylvania.
4. GSK LLC is an indirect wholly-owned subsidiary of GlaxoSmithKline PLC ("GSK PLC").

Exhibit

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5. GSK LLC and GSK PLC maintain all the formalities of separate corporations. GSK LLC maintains books and records, payrolls, bank accounts, and a board of directors independently of GSK PLC. GSK LLC and GSK PLC are separately and adequately capitalized.

6. At all relevant times (at least from 2001 – present) GSK LLC is not, and has not been, a direct or indirect shareholder of GlaxoSmithKline (China) Investment Co., Limited (“GSK China”).

7. At least from 2013 – present, GSK LLC has had no commercial operations in China.

8. None of the GSK-affiliated individuals who are referred to in the complaint (“Complaint”) that was filed in connection with this litigation were employed by GSK LLC or otherwise performed services on behalf of, or directed towards, GSK LLC during the relevant time period (April through July 2013) set forth in the allegations:

- a. Mark Reilly;
- b. April Zhao;
- c. Jennifer Huang;
- d. Leslie Chang;
- e. Brian Cahill;
- f. June Soon; and
- g.. Maggie Zheng.

9. GSK LLC was not a party to the April 25, 2013 Consultancy Agreement, including all appendices, entered into between GSK China (Investment) Co. Ltd. (“GSK China”) and ChinaWhys, through the ChinaWhys alter egos ChinaWhys (Shanghai) Consulting Co. Ltd. and ChinaWhys Co. Ltd., which is the subject of the within litigation.

10. On July 2, 2012, GSK LLC agreed to plead guilty and to pay \$3 billion to resolve criminal and civil liabilities arising from the promotion of certain prescription drugs, the failure to report certain safety data, and its civil liabilities for alleged false price reporting practices, arising from various conduct that occurred in the United States between 1994 - 2010 ("2012 U.S. Settlement"). Neither GSK China nor GSK PLC were parties to the 2012 U.S. Settlement.

11. On September 19, 2014, the Changsha Intermediate People's Court in Hunan Province, China entered a judgment against GSK China for approximately \$489.5 million in connection with violations by GSK China personnel of Chinese law prohibiting bribery of non-governmental Chinese personnel ("2014 China Judgment"). GSK LLC was not a party to the 2014 China Judgment.

12. On September 30, 2016, the United States Securities and Exchange Commission ("U.S. SEC") and GSK PLC entered into a civil resolution concerning internal controls and recordkeeping provisions of the United States Foreign Corrupt Practices Act of 1977 relating to conduct in China by GSK China and a related joint-venture ("2016 U.S. Settlement"). GSK LLC was not a party to the 2016 U.S. Settlement.

\* \* \*

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

DATE:

*January 13, 2017*



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## Conviction of private investigators in China further complicates anti-corruption compliance efforts

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**China, USA** | August 19 2014

The recent convictions of Peter Humphrey and his wife and business partner Yu Yingzeng demonstrate the risks corporate investigation firms face in China when they obtain or pass on information on Chinese citizens. But perhaps even more alarming for U.S. companies is the effect of such prosecutions on their efforts to comply with the Foreign Corrupt Practices Act and other anti-corruption laws, as these types of convictions stand to have a chilling effect on both companies' due diligence efforts and their internal investigations into allegations of bribery and fraud in China.

Mr. Humphrey, a British citizen, and Ms. Yu, a Chinese citizen, were convicted of trafficking in personal information of Chinese citizens between 2009 and 2013 through their company ChinaWhys. ChinaWhys, which still operates an up-to-date website, markets itself as "an international business risk advisory firm with eyes in China." It offers services from "due diligence and the discreet gathering of timely business intelligence, to the vetting of partners and the screening of employees." It specifically references corruption investigations on its website. Mr. Humphrey, himself a Certified Fraud Examiner, has written extensively on the issues facing companies in China, including under the anti-corruption laws, and the ways forensic firms can assist companies to comply with their legal obligations. ChinaWhys is one of many firms in China that seeks to assist companies in conducting background checks and other due diligence, which can be more difficult in China than in other jurisdictions.

Chinese officials claimed that Mr. Humphrey and Ms. Yu had, through ChinaWhys, illegally obtained the "personal household registrations" of Chinese citizens, or "hukous," as well as other personal information, for a price of \$130 to \$163 for each item, which they packaged into reports they sold at great profit. While it was not discussed at trial, ChinaWhys boasted many large multinational corporations as clients and may have been assisting those clients in Foreign Corrupt Practices Act compliance or investigations work. Mr. Humphrey was sentenced to two and one half years in prison (including one year served while awaiting trial) and a fine of £20,000, while Ms. Yu was sentenced to two years in prison and a £15,000 fine.

The convictions reflect the challenges companies can face in conducting and maintaining appropriate due diligence in China under the FCPA or other anti-corruption laws. Those laws require companies to investigate potential third-party consultants, agents and business partners to ensure, among other things, that they are not (and do not have improper relationships with) government officials. Companies are also encouraged to investigate allegations of anti-corruption violations swiftly and completely, and to self-report them to the authorities. The public prosecution of

Ca

Exhibit

15

individuals and companies in China for violating laws related to the collection of personal information is a deterrent to this type of diligence and reporting, because companies are now not only going to be hesitant to reach out to companies like ChinaWhys to assist in conducting due diligence, but they may also find that there are fewer companies out there in China that are willing to assist them. By enforcing laws against the collection and disclosure of personal information (allegedly often at the behest of Chinese individuals or companies that stand to lose from such a disclosure), China is imposing yet another roadblock for companies seeking to do business there. In this way, preventing access to background information may actually make it easier for individuals and entities get away with fraud, despite claims by Chinese authorities that the enforcement of privacy laws is meant to combat and root out corruption.

---

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## Foreign couple arrested for selling personal information

08-27-2013 13:50 BJT

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Shanghai police have arrested a foreign couple for illegally obtaining information that infringed upon the privacy of Chinese citizens. This is the first case of foreigners being arrested for privacy infringement in China.

57-year-old Peter Humphrey, from Britain, and 60-year-old Yu Ying Zeng, from the United States, have confessed to breaching privacy laws.

In 2003, they registered Chinawhys Limited, a shell company in Hong Kong. It was the start of a ten year profitable -- but illegal -- business.

Just a year later, they registered another company in Shanghai, and hired a dozen employees.

Every year they earned profits as high as 6 million yuan from about 100 clients.

More than five hundred investigation reports were found among company records, some of them severely infringing on the privacy of Chinese citizens.

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Lu Wei with Criminal Invest, Division of Shanghai Public Security Bureau said, "These mainly include household registration information, vehicle and property information and exit-entry records."

Most of Humphrey and Yu's clients were transnational corporations, including manufacturing companies, financial institutions and law firms.

The couple obtained people's personal information at prices ranging from 800 to 2,000 Yuan.

Using that information, they then sold their investigation reports at more than 10,000 Yuan.

Suspect Peter Humphrey said, "We sometimes use illegal methods to obtain personal information, I very much regret doing this, and I want to apologize to the Chinese government."

The case is still under investigation.

Early in August, Shanghai police arrested 126 people for privacy infringement, 35 of whom are now under criminal detention.

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

---

PETER HUMPHREY, YU YINGZENG, and  
CHINAWHYS COMPANY LTD,

Plaintiffs,

v.

GLAXOSMITHKLINE PLC and  
GLAXOSMITHKLINE LLC,

Defendants.

---

Civil Action No.: 2:16-CV-5924

**DEFENDANTS’ MOTION TO COMPEL ARBITRATION, OR, IN THE  
ALTERNATIVE, MOTION TO DISMISS THE COMPLAINT**

Defendants GlaxoSmithKline plc (“**GSK PLC**”) and GlaxoSmithKline LLC (“**GSK LLC**”) (collectively, “**GSK Defendants**”), through their counsel, move to compel arbitration of the entirety of Plaintiffs’ Complaint pursuant to a written agreement providing for arbitration before the China International Economic and Trade Arbitration Commission (“**CIETAC**”).

In the alternative, GSK PLC, a British entity with no ties to the United States, moves to dismiss the Complaint for lack of personal jurisdiction. GSK PLC does not maintain systematic and continuous contacts with either the United States or the Commonwealth of Pennsylvania, and did not perform any action directed here giving rise to the alleged claims. The Court therefore lacks personal jurisdiction over GSK PLC.

The GSK Defendants additionally move to dismiss the Complaint for failure to state a claim and for failure to join an indispensable party. Plaintiffs’ Complaint pleads no facts giving rise to alleged racketeering, conspiracy, or emotional distress claims against the GSK

Defendants, and Plaintiffs have failed to commence several of those claims within the applicable limitations period. Plaintiffs additionally failed to join GlaxoSmithKline (China) Investment Co. Ltd. (“**GSK China**”), which is a necessary party to this dispute. GSK China is a signatory to the contract containing the provision for mandatory arbitration before the CIETAC, and Plaintiffs alleged claims arise from that contract.

The grounds for this motion are set forth more fully in the attached Memorandum of Law, which is incorporated herein by reference.

Dated: January 16, 2017

Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

---

PETER HUMPHREY, YU YINGZENG, and  
CHINAWHYS COMPANY LTD,

Plaintiffs,

v.

GLAXOSMITHKLINE PLC and  
GLAXOSMITHKLINE LLC,

Defendants.

---

Civil Action No.: 2:16-CV-5924

**DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR  
MOTION TO COMPEL ARBITRATION, OR, IN THE  
ALTERNATIVE, MOTION TO DISMISS THE COMPLAINT**

Defendants GlaxoSmithKline plc (“**GSK PLC**”) and GlaxoSmithKline LLC (“**GSK LLC**”) (collectively, “**GSK Defendants**”), through their counsel, submit the following memorandum in support of their motion to compel arbitration, or in the alternative, motion to dismiss the complaint for lack of personal jurisdiction, failure to state a claim upon which relief can be granted, failure to join an indispensable party, and failure to bring a timely action under Pennsylvania law.

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## I. SUMMARY OF ARGUMENT

Plaintiffs' complaint ("**Complaint**") suffers from multiple overriding defects, any one of which is alone fatal to their claims. Most notably, Plaintiffs commenced this action notwithstanding the fact that their claims are governed by a binding agreement ("**Consultancy Agreement**") requiring that the parties "*submit the dispute to the China International Economic and Trade Arbitration Commission*" ("**CIETAC**") in Beijing for arbitration." (See Ex. 1, Consultancy Agreement, at § 11.) The Court should enforce that arbitration clause, and should stay all proceedings pending conclusion of the CIETAC arbitration, at which point judgment should be entered in accordance with any arbitral award.

Notwithstanding the mandatory referral to arbitration, Plaintiffs' claims fail on the merits and, as to GSK PLC, on jurisdictional grounds. Plaintiffs attempt to mount racketeering, fraud, conspiracy and emotional distress claims against the GSK Defendants by stringing together allegations that, on their face, do not pertain to, and were not committed by either defendant. Plaintiffs have identified no basis to impute any alleged activities to the GSK Defendants, nor have they identified any link between GSK PLC, (a United Kingdom ("**U.K.**") entity formed under British law) and the United States ("**U.S.**") that would support exercising personal jurisdiction over GSK PLC.

Lastly, Plaintiffs have failed to join GlaxoSmithKline (China) Investment Co. Ltd. ("**GSK China**"), the signatory to the Consultancy Agreement containing the binding arbitration provision and an indispensable party to this lawsuit. A full and fair adjudication on the merits of this matter cannot occur without GSK China's participation.

Accordingly, the Court should grant the GSK Defendants' motion to compel arbitration and require Plaintiffs to proceed with their claims before the CIETAC. Alternatively, the Court should dismiss the claims against GSK PLC for lack of jurisdiction, and should otherwise

dismiss the entirety of Plaintiffs' Complaint for failure to state a claim upon which relief can be granted, failure to join an indispensable party, and failure to bring a timely action under Pennsylvania law.

## II. PRELIMINARY STATEMENT

This lawsuit is at its core a dispute between Peter Humphrey ("**Humphrey**"), Yu Yingzeng ("**Yu**") and ChinaWhys Company Ltd. ("**ChinaWhys Ltd**") (collectively, "**Plaintiffs**") against a non-party/separate GSK entity, GSK China, regarding a Consultancy Agreement signed in China, for services to be provided in China which is governed by Chinese law and subject to a binding arbitration provision; but the lawsuit has been improperly commenced in a U.S. federal court by Plaintiffs against two unrelated GSK entities, GSK PLC and GSK LLC (the GSK Defendants), which have no connection to the Consultancy Agreement or to the dispute. Plaintiffs' Complaint violates an enforceable and binding agreement to arbitrate, and thus requires dismissal of this action. Further, Plaintiffs' effort to bring a China-based dispute in this forum creates insurmountable jurisdictional and standing hurdles and leaves them unable to articulate plausible claims against the entities they chose to sue in this Court.

Plaintiffs' allegations arise out of services provided to GSK China pursuant to an April 25, 2013 Consultancy Agreement entered into between GSK China and ChinaWhys (Shanghai) Consulting Co. Ltd. ("**ChinaWhys (Shanghai)**"). (*See* Ex. 1, Consultancy Agreement & App'x A.)<sup>1</sup> Under this agreement, GSK China retained ChinaWhys for due diligence and investigation services following a security incident at a GSK China executive's apartment in March 2013. GSK China engaged ChinaWhys to investigate the circumstances of

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<sup>1</sup> As explained in greater detail in Section III(C), all references herein to ChinaWhys ("**ChinaWhys**") will refer collectively to the named plaintiff in this lawsuit, ChinaWhys Ltd, as well as ChinaWhys (Beijing), ChinaWhys (Shanghai), ChinaWhys (Hong Kong), and all other consulting companies co-founded and co-owned by Humphrey and Yu. *See, infra*, Section III(C).

the security incident and the potential involvement of a former employee (Vivian Shi (“**Shi**”)). Under Section 11 of the Consultancy Agreement, the parties agreed that any disputes that arose would be governed by the laws of China, and would be submitted to CIETAC. (*See* Ex. 1, Consultancy Agreement § 11.)

Specifically, Section 11 of the Consultancy Agreement, entitled “Governing Law and Dispute Resolution,” provides:

This Agreement shall be governed in all respects by the laws of the People’s Republic of China. *All disputes arising out of or in connection with this Agreement shall be settled through friendly consultation between both parties. In case no settlement can be reached, either Party may submit the dispute to the China International Economic and Trade Arbitration Commission (“CIETAC”) in Beijing for arbitration in accordance with the CIETAC rules of arbitration then in effect. The arbitration award shall be final and binding* on the Parties.”

(*Id.*)

Section 1.6 of the Consultancy Agreement further provides:

[ChinaWhys] shall carry out the Consulting Services *always in a lawful and ethical manner*. The term ‘ethical’ used in the policy means: *in compliance with all laws, regulations, legal and professional guidelines*, and in a manner not likely to result in harm to GSK’s reputation or image.”

(*Id.* at § 1.6.)

On or around July 10, 2013, ChinaWhys’ co-founders and co-managers, husband/wife Humphrey and Yu, were detained by the Shanghai police on suspicion of violating Chinese laws relating to the purchase of personal information and data. They were arrested on August 16, 2013 and charged with trafficking in private records of Chinese individuals. (*See* Ex. 2.) Plaintiffs now attempt to blame their personal and business injuries arising from their arrest, conviction and incarceration on GSK, alleging that it was somehow their performance of services for GSK that caused their arrest.

Plaintiffs fail to disclose in their Complaint that in 2013, less than two months before he and Yu were arrested by the Chinese authorities, Humphrey published an article explicitly criticizing the Chinese government for newly promulgated rules and regulations restricting access to personal information. (*See* Ex. 3.)<sup>2</sup> In that article, Humphrey described recent crackdowns in May 2012 and January 2013 by the Chinese government, and new regulations promulgated in February 2013, which further enforced laws regarding access to and dissemination of personal information, noting specifically that this had led to “more than 1,000 local investigators and their alleged sources . . . [being] detained.” (*Id.*) As evidenced by the article, Humphrey was well aware of Chinese legal restrictions governing the use of personal information, and the risks that he and other investigators faced if they failed to comply with these restrictions. Simply put, Humphrey failed to heed his own warnings. The GSK Defendants had nothing to do with Humphrey’s article or this failure to comply with Chinese law. To the contrary, the Consultancy Agreement specifically required ChinaWhys to conduct its work under the engagement in accordance with Chinese law. (*See* Ex. 1, Consultancy Agreement at § 1.6.) Humphrey, Yu and ChinaWhys, upon their own initiative and despite knowledge of the risks, chose to disregard this requirement.

Plaintiffs instead attempt to spin a tale of a global racketeering enterprise and conspiracy involving GSK PLC and GSK LLC, claiming that their mistreatment in China in 2013 was somehow related to the marketing of pharmaceutical products in the U.S. in 1999 and to the resolution between GSK LLC and the U.S. Health & Human Services Department

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<sup>2</sup> P. Humphrey, The Fraud Examiner, “How Fraud Investigation Just Got Harder in China: Exploring the Impact of China’s Clampdown on Public Records” (May 2013), *available at* <http://www.acte.com/fraud-examiner.aspx?id=4294978054>.

(“**2012 U.S. Settlement**”);<sup>3</sup> this in order to insinuate a U.S. nexus and attempt to implicate the U.S. Racketeer Influenced and Corrupt Organizations Act (“**RICO**”), stretching RICO well beyond the breaking point of rational interpretation. The subject matter involved in the 2012 U.S. Settlement ended in 2010 (and much of it earlier than that), many years before ChinaWhys had involvement with GSK China or entered into the Consultancy Agreement in April 2013. Likewise, Plaintiffs’ allegations that a subsequent 2013 investigation in China and related attention from U.S. regulators are part of a common scheme are also baseless. The China and U.S. investigations involved conduct unrelated to the Humphrey and Yu claims and were fully resolved by GSK China and the Chinese government on September 19, 2014 (“**2014 China Judgment**”),<sup>4</sup> and by GSK PLC and the U.S. Securities and Exchange Commission (“**U.S. SEC**”) on September 30, 2016 (“**2016 U.S. Settlement**”).<sup>5</sup> Plaintiffs’

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<sup>3</sup> On July 2, 2012, GSK LLC agreed to plead guilty and to pay \$3 billion to resolve criminal and civil liabilities arising from the promotion of certain prescription drugs, failure to report certain safety data, and civil liabilities for alleged false price reporting practices. (*See* Ex. 4, Press Release, U.S. Dep’t of Justice, GlaxoSmithKline to Plead Guilty to Pay \$3 Billion to resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), Ex. 5, Corporate Integrity Agreement, Office of Inspector General of the Dep’t of Health and Human Services and GlaxoSmithKline LLC (July 2, 2012).) This criminal and civil liability arose from conduct that occurred in, and was directed towards, the U.S. between 1994 and 2010. The settlement resolved claims relating to activities in the U.S. for Paxil, Wellbutrin, Avandia, Advair and other products, as well as allegations of false price reporting under the U.S. Federal Medicaid Rebate Program. (*Id.*) The 2012 U.S. Settlement does not relate to any matters in China. (*Id.*)

<sup>4</sup> On September 19, 2014, the Changsha Intermediate People’s Court in Hunan Province, China entered the 2014 China Judgment against GSK China for approximately \$489.5 million in relation to conduct implicating Articles 67 and 164 of the Criminal Law of the People’s Republic of China, which prohibit offering money or property to non-governmental Chinese personnel in order to obtain improper commercial gains. (*See* Ex. 6, Press Release, GlaxoSmithKline, GSK China Investigation Outcome (Sept. 19, 2014).) Neither GSK LLC nor GSK PLC were parties to, or the subjects of, the 2014 China Judgment. (*Id.*)

<sup>5</sup> On September 30, 2016, the U.S. SEC and GSK PLC entered into the 2016 U.S. Settlement, in a civil resolution of the recordkeeping and internal controls provisions of the U.S. Foreign Corrupt Practices Act of 1977. (*See* Ex. 7, Press Release, GlaxoSmithKline Pays \$20 Million Penalty to Settle FCPA Violations (Sept. 30, 2016), Ex. 8, *In the Matter of GlaxoSmithKline plc*, A.P. No. 3-17606, Order (Sept. 30, 2016).) The resolution mentions specific violations relating to conduct by GSK PLC’s indirect subsidiary, GSK China, between 2010 and June 2013. (*Id.*) GSK PLC was named as a party, not based on any conduct related to the settlement but solely because its American Depositary Receipts are registered with the U.S. SEC under Section 12(b) of the Securities Exchange Act and trade on the New York Stock Exchange under the symbol “GSK,” and its consolidated books and records and internal controls, which relate to the activities of all wholly-owned subsidiaries, were rendered inaccurate or revealed to be insufficient as a result of conduct by GSK China. Neither GSK LLC nor GSK China were parties to the 2016 U.S. Settlement. Nor was any conduct in China by GSK PLC itself at issue in the settlement. The 2016

allegation that these unrelated events were part of a common scheme not to comply with laws at issue with respect to the convictions of Humphrey and Yu in China or to “cover up” the activities of GSK in China is baseless on its face.

Finally, Plaintiffs’ decision not to name GSK China as a defendant in an action involving the very Consultancy Agreement which they entered into with GSK China can be no accident. Plaintiffs intentionally omitted this indispensable party in an effort to circumvent the mandatory arbitration provision of the Consultancy Agreement and to avoid the jurisdictional obstacles that would foreclose a lawsuit in the U.S. against the only GSK entity with which they actually interacted.

### **III. FACTUAL BACKGROUND**

Plaintiffs’ Complaint alleges six causes of action: (1) violations of 18 U.S.C. § 1962(c) (Racketeering), (2) violations of 18 U.S.C. § 1962(d) (Conspiracy), (3) fraud, (4) intentional infliction of emotional distress, (5) negligent infliction of emotional distress and (6) civil conspiracy. (*See e.g.*, Compl. ¶¶ 121-137, 137-149, 150-156, 157-163, 164-170, 171-175.)

#### **A. Consultancy Agreement**

Although Plaintiffs referred only in a nuanced way to the Consultancy Agreement in the Complaint, all of their claims necessarily arise from services that ChinaWhys contracted in April 2013 to provide GSK China. (Comp. ¶¶ 49-90.) GSK China had no other dealings with Plaintiffs. The GSK Defendants were not parties to the Consultancy Agreement. (*See* Ex. 1, Consultancy Agreement.)

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U.S. Settlement was based on the same conduct implicated in the 2014 China Judgment; the U.S. SEC declined to impose any additional disgorgement beyond that already captured by the Chinese judgment. GSK LLC, including its employees, agents and contractors, was not a participant or connected in any way to the matters that occurred in China, and thus it was not a party to the 2016 U.S. Settlement.

Section 11 of the Consultancy Agreement mandates arbitration of all disputes arising out of or in connection with the agreement as follows:

This Agreement *shall be governed in all respects* by the laws of the Peoples Republic of China. All disputes arising out of or in connection to this Agreement shall be settled through friendly consultation between both parties. In case no settlement can be reached, either party may submit the dispute to the China International Economic and Trade Commission (“CIETAC”) in Beijing for arbitration in accordance with the CIETAC rules of arbitration then in effect. *The arbitration award shall be final and binding on the parties.*

(See Ex. 1, Consultancy Agreement § 11.)

#### **B. GSK China: Party to Consultancy Agreement**

The only GSK-related party to the Consultancy Agreement was GSK China, a wholly-owned indirect subsidiary of GSK PLC. (See Ex. 9, GSK China Decl., at ¶ 3.) GSK China, however, is not named as a party in the Complaint. GSK China is incorporated under Chinese law. (*Id.*) Notwithstanding the corporate relationship between GSK China and GSK PLC, they maintain all the formalities of separate corporations. (*Id.* at ¶ 4.) GSK China maintains books and records, payrolls, bank accounts and a board of directors independently of GSK PLC. (*Id.*) Moreover, GSK China and GSK PLC are separately and adequately capitalized. (*Id.*) GSK China’s principal place of business is in Shanghai, China. (*Id.* at ¶ 5.) It has never conducted commercial operations in the United States or the Commonwealth of Pennsylvania. (*Id.* at ¶ 6.)

On behalf of GSK China, the Consultancy Agreement was approved by Mark Reilly (“**Reilly**”), then-general manager of GSK China. (See Ex. 1.) Reilly’s responsibilities and job function related solely to GSK China’s business in China. (See Ex. 9, GSK China Decl. at ¶ 8.) GSK China was the GSK entity which executed the Consultancy Agreement entered into between GSK China and ChinaWhys through the ChinaWhys alter egos ChinaWhys (Shanghai) Consulting Co. Ltd. and ChinaWhys Co. Ltd. (*Id.* at ¶ 7.)

According to the Complaint, ChinaWhys interacted with the following GSK-affiliated employees during the negotiations, execution and performance of the Consultancy Agreement: Mark Reilly (General Manager, GSK China), Maggie Zheng (Administrative Assistant to Mark Reilly, GSK China), April Zhao (former Legal Director, GSK China), Jennifer Huang (former Senior Counsel, Legal Department, GSK China R&D Company Ltd), Leslie Chang (Head of Business Development and Office of the General Manager, GSK China), Brian Cahill (“**Cahill**”) (former GSK Pte. Ltd (Singapore) Senior Vice President and General Counsel, Asia), and June Soon (“**Soon**”) (Executive Secretary, GSK Pte. Ltd (Singapore)). (*See e.g.*, Compl. ¶¶ 50, 64, 70, 79, 80, 82, 83, 84, 86, 87, 88, 89.) Cahill and his assistant Soon were both based in Singapore, and all of the other above-referenced GSK employees were based in China. (*See* Ex. 9, GSK China Decl. at ¶¶ 8-11.) None of those individuals were employed by either of the GSK Defendants.

### **C. ChinaWhys Entities: Party to Consultancy Agreement**

Although ChinaWhys Ltd is the entity named in the Complaint as a plaintiff, ChinaWhys (Shanghai) was the specific party to the Consultancy Agreement. (*See* Ex. 1.) According to the Complaint, ChinaWhys Ltd was co-founded by Humphrey and Yu. (*See* Compl. ¶¶ 6-7.) The ChinaWhys website indicates that Humphrey incorporated ChinaWhys Ltd in Hong Kong in 2003. (*See* Ex. 10.) As ChinaWhys’ managing director, Humphrey signed the Consultancy Agreement and Appendix A, which was incorporated by reference on behalf of ChinaWhys (Shanghai). (*See* Ex. 1.)

The Complaint does not identify ChinaWhys Ltd’s place of incorporation or principal place of business. (*See* Compl. ¶¶ 6-8.) A website purporting to be that of ChinaWhys, however, identifies Humphrey and Yu as the co-founders of a consulting company referred to only

as “ChinaWhys,” and states that this entity is incorporated in Hong Kong. (*See* Exs. 10-12).<sup>6</sup> Notably, the website also refers to the company’s motto as: “Connecting the dots . . . for businesses in China.”

According to its website, ChinaWhys is a “China-based professional-services consultancy providing specialized risk mitigation solutions, consulting and investigation services to corporate clients in sensitive matters across Greater China and Asia.” (*See* Ex. 10 ChinaWhys Website.) The website also represents to the public that ChinaWhys provides “regular advice to businesses on risk management and ha[s] conducted services in China for large, medium and small multinationals, professional services firms, NGOs, chambers of commerce and high wealth individuals, and further that it offers a “cost-effective practice centered on Greater China.” (*Id.*)

#### **D. GlaxoSmithKline plc**

Although it is not a party to the Consultancy Agreement or responsible for the services rendered by ChinaWhys, GSK PLC is named as a defendant in the Complaint. (*See* Ex. 13, GSK PLC Decl. ¶ 17.) None of the GSK employees referred to in the Complaint were employed by GSK PLC. (*Id.* ¶ 18.)

GSK PLC is a public limited company organized under the laws of England and Wales, with its principal place of business at 980 Great West Road, Brentford, Middlesex TW8 9GS, England. (*Id.* at ¶ 3.) GSK PLC was created and exists solely for the purpose of holding the stock of its subsidiaries, through several layers of wholly owned subsidiaries. (*Id.* at ¶ 4.) GSK PLC is not incorporated under the laws of the Commonwealth of Pennsylvania. (*Id.* at ¶ 3.) GSK PLC has never conducted commercial operations anywhere in the world, including the United States and the Commonwealth of Pennsylvania. (*Id.* at ¶ 5.) GSK PLC has never designed,

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<sup>6</sup> *See generally* ChinaWhys Company Website, available at [chinawhys.com/index.htm](http://chinawhys.com/index.htm).

developed, manufactured, marketed or sold any products or services anywhere in the world, including the United States and the Commonwealth of Pennsylvania. (*Id.* at ¶ 6.) GSK PLC is not and has never been a direct shareholder of GSK LLC. (*Id.* at ¶ 7.) GSK PLC and GSK LLC maintain all the formalities of separate corporations. (*Id.* at ¶ 8.) GSK PLC and GSK LLC do not maintain common books and records, payrolls, bank accounts, or boards of directors. GSK LLC and GSK PLC are separately and adequately capitalized. (*Id.*) Similarly, GSK PLC and GSK China also maintain all of the formalities of separate corporations. (*Id.* at ¶ 9.)

#### **E. GlaxoSmithKline LLC**

GSK LLC likewise was not a party to the Consultancy Agreement (including all appendices entered into between GSK China and ChinaWhys) nor was it responsible for the services rendered by ChinaWhys. (*See* Ex. 14, GlaxoSmithKline LLC Decl., at ¶ 9.) GSK LLC is a limited liability company organized in the state of Delaware, with corporate operations in Research Triangle Park, North Carolina and Philadelphia, Pennsylvania. (*Id.* at ¶ 3.) GSK LLC is an indirect wholly-owned subsidiary of GSK PLC. (*Id.* at ¶ 4.) GSK LLC and GSK PLC maintain all the formalities of separate corporations. (*Id.* at ¶ 5.) GSK LLC maintains books and records, payrolls, bank accounts, and a board of directors independently of GSK PLC. GSK LLC and GSK PLC are separately and adequately capitalized. (*Id.*)

At all relevant times (at least from 2001 through present), GSK LLC is not, and has not been, a direct or indirect shareholder of GSK China. (*Id.* at ¶ 6.) At least from 2013 through present, GSK LLC has had no commercial operations in China. (*Id.* at ¶ 7.) None of the GSK-affiliated individuals who were referred to in the Complaint were employed by GSK LLC or otherwise performed services on behalf of, or directed towards, GSK LLC during the relevant time period (April through July 2013). (*Id.* at ¶ 8.) At least from 2013 through the present, GSK LLC has had no commercial operations in China. (*Id.* at ¶ 7.)

The relationships between the relevant ChinaWhys and GSK entities is summarized by the diagram on the following page.

**F. Arrest/Conviction of Humphrey and Yu**

Humphrey and Yu were convicted of the charges against them. (*See*

Ex. 15.) Following his arrest, in a CCTV report, Humphrey was quoted in the media as saying, “We sometimes use illegal methods to obtain personal information. I very much regret doing this, and I want to apologize to the Chinese government.” (*See* Ex. 16.)

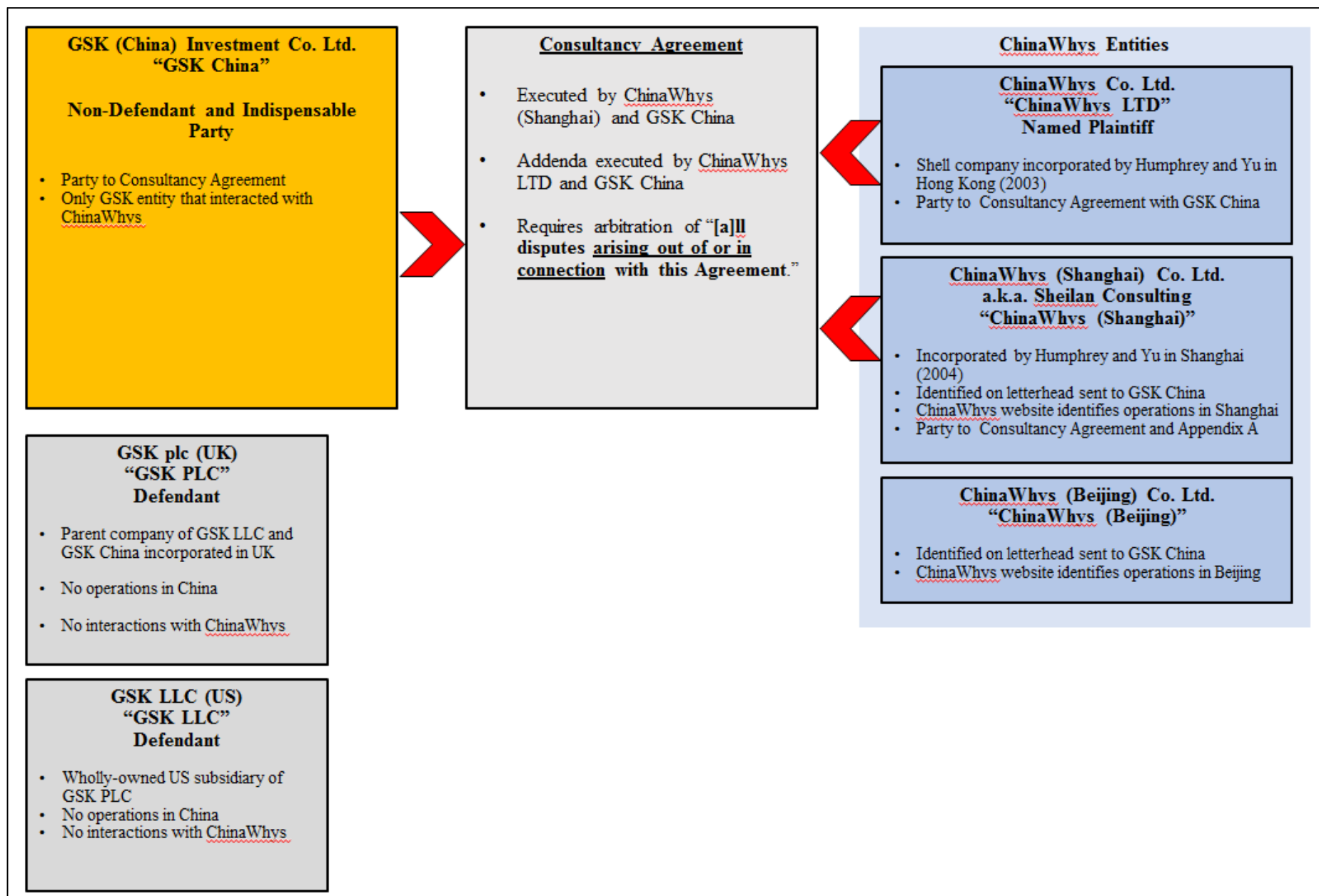
Humphrey was sentenced to two-and-one-half years in prison, and fined £20,000. While Yu was sentenced to two years in prison, and fined £15,000. (Compl. ¶ 97;

Ex. 15 CCTV Article (Aug. 27, 2013).) Humphrey and Yu were released from prison in or around June 9, 2015, and thereafter departed China on June 17, 2015. (Compl. ¶¶ 105-06.)

**IV. ARGUMENT**

**A. The Court Should Compel Arbitration Of The Present Dispute Under The Federal Arbitration Act And The United Nations Convention On The Recognition And Enforcement Of Foreign Arbitral Awards, And Should Stay All Proceedings Pending Completion Of Arbitration**

The arbitration of disputes in this matter is governed by the Federal Arbitration Act (“FAA”). The FAA embodies “a strong federal policy in favor of resolving disputes through arbitration.” *Invista S.A.R.L. v. Rhodia, S.A.*, 625 F.3d 75, 83-84 (3d Cir. 2010). A “written provision in a ... commercial contract showing an agreement to settle disputes by arbitration ‘shall be valid, irrevocable, and enforceable, save upon such grounds as exist in law or equity for the revocation of any contract.’” *Just B. Method, LLC v. BSCPS, LP*, No. 14-1516, 2014 WL 5285634, at \*4 (E.D. Pa. Oct. 14, 2014) (Alejandro, J.) (*quoting Century Indem. Co. v. Certain Underwriters at Lloyd’s London*, 584 F.3d 513, 522 (3d Cir. 2009) and 9 U.S.C. § 2)).



**Figure 1.** Relationship of Relevant GSK and ChinaWhys Entities.

The FAA's second chapter implements the United Nations New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards ("**New York Convention**"), which provides for enforcement and recognition of arbitration provisions in international commercial contracts. Under that chapter, a court will enforce such provisions "if they arise from commercial, legal relationships, such as commercial contracts, except when those relationships are entirely between United States citizens and otherwise are domestic in nature."<sup>7</sup> *Century Indem. Co.*, 584 F.3d at 523 (citing 9 U.S.C. § 202). Together, the FAA and the New York Convention recognize an "emphatic federal policy in favor of arbitral dispute resolution." *Mitsubishi Motors Corp. v. Soler Chrysler-Plymouth, Inc.*, 473 U.S. 614, 631 (1985); *see also Shearson/American Exp., Inc. v. McMahon*, 472 U.S. 220, 226 (1987) ("The Arbitration Act thus establishes a federal policy favoring arbitration, requiring that "we rigorously enforce agreements to arbitrate.") (internal citations and quotations omitted).

When a court is requested to compel arbitration under the New York Convention, it must consider the following four factors, adopted by the U.S. Court of Appeals for the Third Circuit in *Standard Bent Glass Corp. v. Glassrobots Oy*, 333 F.3d 440 (3d Cir. 2003):

- (1) Is there "an agreement in writing to arbitrate the subject of the dispute"?
- (2) "Does the agreement provide for arbitration in the territory of a signatory of the Convention?"
- (3) "Does the agreement arise out of a legal relationship, whether contractual or not, which is considered as commercial?"
- (4) "Is a party to the agreement not an American citizen, or does the commercial relationship have some reasonable relation with one or more foreign states."

*Standard Bent Glass*, 333 F.3d at 449 & n.13; *accord Century Indem. Co.*, 584 F.3d at 523 n.8.

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<sup>7</sup> "The domestic FAA applies to actions brought under the New York Convention to the extent that the two are not in conflict." *See* 9 U.S.C. § 208.

“If the answers are all in the affirmative, the court must order arbitration unless it determines the agreement is null and void.” *Standard Bent Glass*, 333 F.3d at 449 & n.13.

1. All Four Of The *Standard Bent Glass* Factors Favor Arbitration.

i. *A Written Agreement Exists Between The Parties To Arbitrate The Subject Of The Dispute.*

To obtain an order compelling arbitration under the New York Convention, a party must show the existence of a written agreement to arbitrate the subject of the dispute. *Standard Bent Glass Corp.*, 333 F.3d at 449. Here, Section 11 of the Consultancy Agreement broadly states that “[a]ll disputes arising out of or in connection with” the agreement are subject to arbitration. (Ex. 1 Consultancy Agreement § 11.) Clauses using this same or similar formulations give rise to “a presumption of arbitrability” under which arbitration “*should not be denied unless it may be said with positive assurance that the arbitration clause is not susceptible of an interpretation that covers the asserted dispute.*” *Moses H. Cone Mem. Hosp. v. Mercury Constr. Corp.*, 460 U.S. 1, 24 (1983) (emphasis added); *see also Hinnant v. Am. Ingenuity, LLC*, 554 F. Supp. 2d 576, 587 (E.D. Pa. 2008) (holding that a clause providing for arbitration of “all disputes in connection with this contract” created a broad presumption of arbitrability).

Plaintiffs cannot meet that exacting standard. Any claims Plaintiffs allege must ultimately arise out of or in connection to the engagement. According to the Complaint, Plaintiffs were retained by GSK China following a meeting with company representatives. (See Compl. ¶ 50.) That meeting produced the Consultancy Agreement, which provided for due diligence and investigative services including inquiries into Shi (See Ex. 1, Consultancy Agreement § 1.1.) Plaintiffs’ efforts to carry out their duties under the Consultancy Agreement are the only activities that they could have performed in relation to *any* GSK entity. To wit, Plaintiffs’ own allegations link their arrest to GSK. (See Compl. ¶ 91.) As such, according to

their own allegations, any claims Plaintiffs could assert would necessarily arise out of or relate to the Consultancy Agreement.

Plaintiffs' election to style their claims under RICO and state tort law does not abrogate the arbitrability of those claims. As the U.S. Court of Appeals for the Third Circuit has recognized: "If the allegations underlying the claims touch matters covered by [an arbitration clause in a contract], then those claims must be arbitrated, whatever the legal labels attached to them." *Brayman Const. Corp. v. Home Ins. Co.*, 319 F.3d 622, 626 (3d Cir. 2003) (alteration in original) (quoting *Genesco, Inc. v. T. Kakiuchi & Co.*, 815 F.2d 840, 846 (2d Cir. 1987)). In fact, the *Genesco* case upon which the Third Circuit relied in reaching that conclusion expressly found that RICO claims fell within the scope of a broad arbitration provision because "[t]he wire, mail, and transportation fraud allegations which form the predicate acts of [the] RICO claim all derive from the parties' transactions under the [applicable] agreements." *Genesco*, 815 F.2d at 848. The same is true here. As set forth in the Complaint, the various mail and wire frauds allegedly perpetrated by the GSK Defendants were purportedly made to "induce [Plaintiffs] to carry out an investigation that served GSK's political goals." (*See* Compl. ¶ 127.) An undisclosed number of those communications were allegedly made "with Humphrey, Yu, and other ChinaWhys employees" for the purpose of "inducing them to carry out an [allegedly] contrived investigation" for the GSK Defendants. (*See* Compl. ¶ 128(c).) The present dispute therefore "aris[es] out of or in connection with" that Consultancy Agreement and is subject to its broad arbitration provision. (*See* Ex. 1, Consultancy Agreement § 11.)

The arbitration clause is mandatory; the use of the word "may" does not render it permissive or discretionary. As one court has explained:

[T]his Court does not distinguish between the use of the term "may" or "shall" in the arbitration context. Instead, we generally recognize that

the language permitting either party to demand arbitration operates to require the parties to submit to arbitration, as it clearly demonstrates that the parties contemplated the use of arbitration proceedings as the forum for resolution of disputes.

*D & H Distrib. Co. v. Nat'l Union Fire Ins.*, 817 A.2d 1164, 1169 (Pa. Super. Ct. 2003). This Court too has “rejected ... argument[s] that the use of the word ‘may’ automatically renders an arbitration clause permissive.” Under the prevailing interpretation, “arbitration clauses using the word ‘may’ have been held to compel mandatory arbitration on the grounds that such language merely manifests the parties’ intent that arbitration be obligatory if either party so chooses.” *Brown v. City of Philadelphia*, No. 10-2687, 2010 WL 4484630, at \*5 (E.D. Pa. Nov. 9, 2010); *see also American Italian Pasta Co. v. Austin Co.*, 914 F.2d 1103, 1104 (8th Cir. 1990); *Sidorek v. Chesapeake Appalachia LLC*, 3:13-CV-0208, 2014 WL 1218893, at \*3 (M.D. Pa. Mar. 24, 2014).

The same rationale applies here. The provision in the Consultancy Agreement that “either Party may submit the dispute” to arbitration evinces an intent that a demand for arbitration will be binding once made by either party. *Brown*, 2010 WL 4484630, at \*5; *Sidorek*, 2014 WL 1218893, at \*3. The mandatory nature of the “friendly consultation” requirement bolsters that conclusion. There would be little reason for the parties to agree to a mandatory conciliation process, but immediately thereafter provide a purely optional arbitration provision that neither party could compel the other to follow. Were that the case, the arbitration provision would be of no effect, as it would merely suggest that the dispute could be submitted to arbitration if the parties agreed to do so after the dispute arose—an avenue that they could pursue without an arbitration clause. *See United States v. Bankers Ins. Co.*, 245 F.3d 315, 321 (4th Cir. 2001) (holding that interpreting “may” as permissive in the arbitration context “would render the arbitration provision meaningless for all practical purposes[,] since parties could always

voluntarily submit [ ] to arbitration.”) (alterations in original; internal quotations omitted). The far more likely scenario is that, “by using the word ‘may,’ both parties were given the power to enforce the arbitration clause.” *In re Winstar Commc’ns*, 335 B.R. 556, 563 (Bankr. D. Del. 2005); *see also United Steelworkers of Am., v. Ft. Pitt Steel Casting*, 598 F.2d 1273, 1279 n.18 (3d Cir. 1979) (finding that the district court did not err in holding that grievance procedures in a collective bargaining agreement were “mandatory despite language in the collective bargaining agreement that the parties ‘may’ invoke those procedures.”).

The present dispute therefore falls within the scope of the Consultancy Agreement’s mandatory arbitration provision. The first *Standard Bent Glass* factor should be answered in the affirmative.

ii. *The Arbitration Agreement Provides For Arbitration In The Territory Of A Signatory State.*

To obtain an order compelling arbitration under the New York Convention, a party must next demonstrate that the agreement at issue provides for arbitration in a signatory state. *Standard Bent Glass Corp.*, 333 F.3d at 449 n.13. Both the U.S. and China are signatories to the Convention. *See* New York Arbitration Convention, Contracting States, available at <https://www.newyorkconvention.org/countries> (last visited January 16, 2017). The Consultancy Agreement specifically provides for application of the laws of the Peoples Republic of China and arbitration before “[CIETAC] in Beijing.” (*See* Ex. 1, Consultancy Agreement § 11.)

The second *Standard Bent Glass* factor is therefore answered in the affirmative.

iii. *The Consultancy Agreement Sets Forth A Legal Relationship That Is Considered Commercial.*

Next, the Court must consider whether the agreement at issue “arise[s] out of a legal relationship ... which is considered as commercial.” *Standard Bent Glass Corp.*, 333 F.3d at 449

n.13. In the arbitration context, courts have broadly construed the term “commercial” to apply to any matter that “‘has a connection with commerce, whether or not that commerce has a nexus with the United States.’” *Belize Social Dev. Ltd. v. Gov’t of Belize*, 794 F.3d 99, 104 (D.C. Cir. 2015) (quoting Restatement (Third) of U.S. Law of Int’l Comm. Arbitration § 1-1 cmt. e); accord *Island Territory of Curacao v. Solitron Devices, Inc.*, 356 F. Supp. 1, 13 (S.D.N.Y. 1973) (“[I]t seems clear that the full scope of ‘commerce’ and ‘foreign commerce,’ as those terms have been broadly interpreted, is available for arbitral agreements and awards.”).

The Consultancy Agreement is a written document setting forth a legal relationship that addresses a commercial matter. It contains provisions under which Plaintiffs would provide professional services to GSK China, outlines the parameters of their work, and provides the terms and conditions under which they were to be paid. It is the quintessential service contract between a service provider and a client. (See Ex. 1, Consultancy Agreement §§ 1.1-1.6, 3.1-3.4.) As such, it represents a commercial arrangement between its signatories and touches on a matter “considered as commercial” for purposes of the New York Convention. *Standard Bent Glass Corp.*, 333 F.3d at 449 n.13. The third *Standard Bent Glass* factor is therefore answered in the affirmative.

iv. *A Party To The Consultancy Agreement Is Not An American Citizen, Or It Has A Reasonable Relationship With A Foreign State.*

Lastly, the Court must determine whether a non-American is a signatory to the agreement at issue, or whether there is “some reasonable relation with one or more foreign states.” *Standard Bent Glass Corp.*, 333 F.3d at 449 n.13. Although only one of those characteristics is needed to compel arbitration, the Consultancy Agreement features both. *Id.* Neither party to the Consultancy Agreement is an American citizen. GSK China is incorporated under Chinese law, maintains its principal place of business in Shanghai, and operates exclusively in China. (See Ex.

9, GSK China Decl. ¶¶ 3-4.) ChinaWhys is formed under the law of Hong Kong. (See Ex. 10.) More importantly, the meeting at which Plaintiffs were retained by GSK China occurred in China, the investigative services provided by Plaintiffs under the Consultancy Agreement were performed in China, and all of the material events giving rise to this action occurred in and were focused on conduct in China. The Consultancy Agreement not only has a reasonable relationship with a foreign state (China), but in fact its only relationship is with China. The final *Standard Bent Glass* factor is therefore answered in the affirmative.

Accordingly, because all four of the *Standard Bent Glass* factors are met, the Court should issue an order compelling arbitration in accordance with the FAA and the New York Convention.

2. No Grounds Exist To Refuse Arbitration Under The Consultancy Agreement.

Once a dispute falls within the scope of the New York Convention, the Court should grant a motion to compel unless it finds that the agreement is “null and void.” *Standard Bent Glass*, 333 F.3d at 449. No such grounds for such a finding exist here.

i. Plaintiffs Have Not Made An Attempt To Invalidate The Consultancy Agreement.

Plaintiffs do not mention the arbitration requirement in their Complaint, much less raise a particularized allegation as to that provision. GSK PLC and GSK LLC are entitled to invoke the arbitration provision of the Consultancy Agreement.

Even though GSK PLC and GSK LLC are not direct signatories to the Consultancy Agreement, they are nonetheless entitled to invoke its arbitration provision. An arbitration clause may be enforced by a nonsignatory if a “close relationship” exists between the entities involved and if “the claims were intimately founded in and intertwined with the underlying contract obligations.” *E.I. DuPont de Nemours*, 269 F.3d at 199. In essence, when a claim arises

by or against one member of a corporate family by virtue of a related company's contract, the non-signatory may invoke any arbitration provision in that contract. *Id.*; see also *Bannett v. Hankin*, 304 F. Supp. 2d 354, 359 (E.D. Pa. 2004) (“[N]onsignatories to an arbitration agreement have standing to compel arbitration against a signatory and the signatory is estopped from avoiding arbitration with a nonsignatory when the issues which the nonsignatory wants to resolve are intertwined with the agreement that the signatory signed.”).

Here, Plaintiffs' claims against GSK PLC and GSK LLC allegedly arose while Plaintiffs were carrying out their investigatory obligations under the Consultancy Agreement with GSK China. (Compl. ¶¶ 49-70.) Those claims are “intimately founded in and intertwined with” the Consultancy Agreement such that GSK PLC and GLK LLC assumed standing to enforce the arbitration provision of that contract. *E.I. DuPont de Nemours*, 269 F.3d at 199. Plaintiffs must, therefore, bring their claims arising from the Consultancy Agreement in an arbitration tribunal regardless of which GSK corporate entities they attempt to pursue as defendants.

- ii. *The Court May Require Humphrey, Yu, And ChinaWhys To Arbitrate Their Claims Due To Their Affiliation With ChinaWhys (Shanghai), Which Is The Signatory To The Consultancy Agreement.*

The Court may compel the Plaintiffs to arbitrate even though the Consultancy Agreement was signed only by Humphrey on behalf of ChinaWhys (Shanghai). “Because arbitration is a creature of contract law, when asked to enforce an arbitration agreement against a non-signatory to the contract, a district court must determine whether the non-signatory individual ‘is bound by that agreement under traditional principles of contract and agency law.’” *Just B. Method*, 2014 WL 5285634, at \*7 (quoting *E.I. DuPont de Nemours & Co. v. Rhone Poulenc Fiber & Resin Intermediaries, S.A.S.*, 269 F.3d 187, 194-95 (3d Cir. 2001)). Under those principles, a party may be compelled to arbitrate under principles of (1) incorporation by reference, (2) assumption

of contractual rights or obligations, (3) agency, (4) alter ego, and (5) estoppel. *Allstate Settlement Corp. v. Rapid Settlements, Ltd.*, 559 F.3d 164, 170 (3d Cir. 2009).

(1) *The Consultancy Agreement Binds Humphrey And Yu Under Principles Of Agency And Estoppel.*

Under agency principles, when a contract signatory retains another individual or entity as an agent to carry out its contractual obligations, claims accruing as a result of the agent's conduct are subject to any arbitration provision contained in the contract. *Pritzker v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 7 F.3d 1110, 1121 (3d Cir. 1993). The Complaint alleges that Humphrey and Yu are co-founders of ChinaWhys (Shanghai), the signatory to the Consultancy Agreement, and that both Humphrey and Yu were acting in their capacity as principals and agents of ChinaWhys at all times relevant to their claims. (*See* Compl. ¶¶ 6, 7.) The Complaint further alleges that Humphrey was introduced to GSK China by a former ChinaWhys client based on the specialized consulting services ChinaWhys provides. (*Id.* ¶ 49.) The Complaint confirms as well that Humphrey and Yu are “employees” of ChinaWhys, and alleges that the GSK Defendants dictated “Humphrey and Yu’s mission” in carrying out the Consultancy Agreement. (*Id.* ¶¶ 63, 128(c) (referring to “Humphrey, Yu, and other ChinaWhys employees”).) The investigation performed by Humphrey and Yu is the same as that described in the scope of work outlined in ChinaWhys’ project proposal. (*See* Ex. 1, Consultancy Agreement App’x A.) Accordingly, Humphrey and Yu were acting as agents of ChinaWhys with regard to the facts alleged in the Complaint, and they are bound by the arbitration clause in the Consultancy Agreement.

Humphrey and Yu are also bound by the arbitration clause in the Consultancy Agreement under an equitable estoppel theory. A non-signatory to a contract may be bound by a contractual arbitration provision “if the non-signatory exploits the agreement containing the arbitration

clause despite never having signed the agreement.” *E.I. DuPont de Nemours*, 269 F.3d at 200. This Court has recognized that, when an individual litigant “[s]eeks to reap the full benefits of [an] Agreement” executed by an entity of which the litigant is a principal, the individual may be compelled to arbitrate claims arising under that agreement. *See Just B Method*, 2014 WL 5285634, at \*9. Here Humphrey and Yu sought to reap the benefits for the work that was performed in China for the purpose of carrying out their obligations under the Consultancy Agreement. The Court should, therefore, compel Humphrey and Yu to arbitrate in accordance with that agreement.

(2) *The Consultancy Agreement Binds ChinaWhys Under Principles Of Alter Ego, Agency, And Assumption Of Contract Rights.*

Under alter ego principles, one corporate entity may be bound by an arbitration clause in a contract signed by an affiliated company when the two entities have so comingled their operations that they function as a single enterprise. *Aluminium Bahrain B.S.C. v. Dahdaleh*, 17 F. Supp. 3d 461, 471 (W.D. Pa. 2014). Similarly, under principles of assumption, one entity may be bound by an arbitration clause if its “subsequent conduct indicates that it is assuming the obligation to arbitrate.” *Invista S.A.R.L.*, 625 F.3d at 85 (internal quotations omitted). Here, Humphrey’s and Yu’s conduct in China was allegedly performed to satisfy ChinaWhys (Shanghai)’s obligations under the Consultancy Agreement, despite the fact that the Complaint attributes that conduct to ChinaWhys and alleges that Humphrey and Yu performed their investigation on ChinaWhys’ behalf. (Comp. ¶¶ 49-70.) ChinaWhys was operating to fulfill ChinaWhys (Shanghai)’s obligation to “initiate inquiries into [Shi] and her contacts.” (See Ex. 1, Consultancy Agreement App’x A, at 4.) The actions of Humphrey and Yu are thus attributable to ChinaWhys (Shanghai), the contract signatory, because the two ChinaWhys entities functioned as a single enterprise using the same personnel.

Alternatively, the Consultancy Agreement binds ChinaWhys under an agency theory because ChinaWhys, through its employees, was acting as the agent of ChinaWhys (Shanghai) to fulfill contractual obligation of the latter entity. “Because a principal is bound under the terms of a valid arbitration clause, its agents, employees, and representatives are also covered under the terms of such agreements.” *Pritzker*, 7 F.3d at 1121.

Moreover, ChinaWhys’ conduct reflects an intent to be bound regardless of any alter ego or agency relationship. ChinaWhys directed its personnel into China for the specific purpose of furthering the relationship between GSK China and ChinaWhys (Shanghai) created by the Consultancy Agreement. By acting on behalf of ChinaWhys (Shanghai) to meet its contractual duties, ChinaWhys manifested its intent to be bound by the contract from which those duties arose. *See Thomson-CSF, S.A. v. Am. Arb. Ass’n*, 64 F.3d 773, 777 (2d Cir. 1995) (“In the absence of a signature, a party may be bound by an arbitration clause if its subsequent conduct indicates that it is assuming the obligation to arbitrate.”).

The Court should find that ChinaWhys is bound by the arbitration provisions of the Consultancy Agreement.

iii. *Arbitration Remains Proper Notwithstanding That Humphrey And Yu Are No Longer In China.*

The Court may compel arbitration notwithstanding that Humphrey and Yu were allegedly “deported from China on June 17, 2015” and are no longer physically present or resident in China. (*See* Compl. ¶ 106.) A contract such as the Consultancy Agreement incorporates into its terms the law existing at the time of its formation. *See DePaul v. Kauffman*, 272 A.2d 500, 506 (Pa. 1971). In this case, the chosen law governing the agreement is the law of China and the chosen forum is CIETAC. (*See* Ex. 1, Consultancy Agreement at § 11.) CIETAC rules provide that “[a] party may be represented by its authorized Chinese and/or foreign representative(s) in

handling matters relating to the arbitration,” even if the party cannot or chooses not to attend the proceeding in person. *See* CIETAC Arb. R. art. 22.<sup>8</sup> By assenting to the arbitration provision in the Consultancy Agreement, Plaintiffs agreed to use and rely upon CIETAC procedures, including those allowing a representative to conduct the arbitration on the party’s behalf. Accordingly, the fact that Humphrey and Yu are not in China should not preclude the Court from granting a motion to compel arbitration in accordance with the Consultancy Agreement.

**B. The Court Must Dismiss All Claims Against GSK PLC For Lack Of Personal Jurisdiction**

1. The Court Cannot Assert General Jurisdiction Over GSK PLC

In order for the Court to assert general personal jurisdiction over a foreign corporation, the corporation’s affiliations with the forum state must be “so constant and pervasive” that it is essentially “at home” there. *Daimler AG v. Bauman*, 134 S. Ct. 746, 751 (2014). Except for “an exceptional case” such as a temporary relocation of a corporate headquarters, a corporation is “at home” only in its formal place of incorporation and its principal place of business. *Id.* at 761.

GSK PLC is a public limited company with its principal place of business in Middlesex, United Kingdom. (*See* Ex. 13, GSK PLC Decl. ¶ 3.) GSK PLC’s sole purpose is to act as a holding company for its global operations through a series of intermediate holding companies responsible for its various divisions. (*Id.* ¶ 4.) GSK PLC has no operations, no sales, no employees, and no other activities in the U.S. (*Id.* ¶ 5.) Accordingly, under *Daimler*, the Court has no basis to assert general jurisdiction over GSK PLC.

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<sup>8</sup> *See also Jiangsu Changlong Chemicals, Co. v. Burlington Bio-Med. & Sci. Corp.*, 399 F. Supp. 2d 165, 169 (E.D.N.Y. 2005) (confirming award over due process objection that company representatives were prevented from obtaining necessary visas to attend Chinese arbitration, when counsel had appeared at arbitration on defendant’s behalf).

## 2. The Court Cannot Assert Specific Jurisdiction Over GSK PLC

Specific jurisdiction focuses on “minimum contacts” between a non-resident defendant and the forum with respect to the claims asserted against it. *Dollar Sav. Bank v. First Sec. Bank of Utah*, 746 F.2d 208, 211-12 (3d Cir. 1984). First, the defendant must have “purposefully directed [its] activities” at the forum. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (quotation marks omitted). Second, the litigation must “arise out of or relate to” at least one of those forum-related activities. *Helicopteros Nacionales de Colombia v. Hall*, 466 U.S. 408, 418 n.8 (1984); *Grimes v. Vitalink Comms. Corp.*, 17 F.3d 1553, 1559 (3d Cir. 1994). Finally, jurisdiction must otherwise “comport with ‘fair play and substantial justice.’” *Burger King*, 471 U.S. at 476.

Thus, for a controversy to “arise out of” or be “related to” the forum state, a corporation’s “suit-related conduct must create a substantial connection with the forum State.” *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014) (emphasis added). Contacts unrelated to the alleged claims will not support jurisdiction. *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 299 (1980) (“[F]inancial benefits accruing to the defendant from a collateral relation to the forum State will not support jurisdiction if they do not stem from a constitutionally cognizable contact with that State.”).

Here, the analysis is straightforward, as the Complaint fails to allege that GSK PLC had any contacts with the forum related to Plaintiffs’ claims. Nor, in fact, have Plaintiffs alleged suit-related conduct in the forum with respect to any of the GSK Defendants. In the absence of any allegations that GSK PLC acted in Pennsylvania with respect to Plaintiffs’ claims, it cannot be subject to this Court’s personal jurisdiction, and all claims against GSK PLC should be dismissed.

**C. The Court Lacks Subject Matter Jurisdiction Over Plaintiffs’ State-Law Claims (Counts III, IV and V)**

Aside from RICO (18 U.S.C. § 1964), Plaintiffs allege only diversity under 28 U.S.C. § 1332 as the basis for this Court’s subject matter jurisdiction.

However, Plaintiffs cannot rely upon diversity jurisdiction to provide this Court with subject-matter jurisdiction over their non-RICO claims. (*Cf.* Compl. ¶¶ 7, 12 (alleging American citizenship of Yu and relying on diversity statute as a basis for jurisdiction).) Under 28 U.S.C. § 1332, a court may assert diversity jurisdiction over suits between “citizens of different states” (U.S.C. § 1332(a)(1)), “citizens of a State and citizens or subjects of a foreign state” (28 U.S.C. § 1332(a)(2)), and “citizens of different States and in which citizens or subjects of a foreign state are additional parties” (28 U.S.C. § 1332(a)(3)). None of these provisions applies here:

In order to be a citizen of a State within the meaning of the diversity statute, a natural person must be both a citizen of the U.S. *and be domiciled within the State*. An American citizen domiciled abroad, while being a citizen of the U.S. is, of course, not domiciled in a particular state, and therefore such a person is ‘stateless’ for purposes of diversity jurisdiction. Thus, American citizens living abroad . . . are neither ‘citizens of a State,’ *see* 28 U.S.C. § 1332(a)(1), nor ‘citizens or subjects of a foreign state,’ *see id.* § 1332(a)(2).

*Swiger v. Allegheny Energy, Inc.*, 540 F.3d 179, 183–84 (3d Cir. 2008).

Yu is not domiciled in the U.S., and is not a citizen of a state within the meaning of the diversity statute. Accordingly, the Court lacks subject-matter jurisdiction over Plaintiffs’ state-law claims (Counts III, IV and V).

**D. The Complaint Fails To State A Claim Upon Which Relief May Be Granted**

Rule 8(a)(2), which applies to all complaints, requires a “short and plain statement” to “show[] that [the plaintiff] is entitled to relief.” Fed. R. Civ. P. 8(a)(2). To meet this requirement, the complaint must be “plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2007). This means a plaintiff must plead sufficient facts to permit the court “to draw the reasonable inference

that the defendant is liable for the misconduct alleged.” *Santiago v. Warminster Township*, 629 F.3d 121, 128 (3d Cir. 2010) (*quoting Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 262 n.27 (3d Cir. 2010)). “[R]ecitals of the elements of a cause of action, supported by mere conclusory statements,” are insufficient. *Id.* (*quoting Iqbal*, 556 U.S. at 667).

Additionally, claims grounded in fraud must be plead with particularity under Fed. R. Civ. P. 9(b). Pursuant to Rule 9(b), a plaintiff averring a claim in fraud must specify “the who, what, when and where details of the alleged fraud.” *District 1199P Health and Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 508, 527 (D. N.J. 2011). Further:

To determine the sufficiency of a complaint in the Third Circuit, a court must take three steps: First, the court must take note of the elements a plaintiff must plead to state a claim. Second, the court should identify allegations that, because they are no more than conclusions, are not entitled to the assumption of truth. Third, where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief.

*Santiago*, 629 F. 3d at 130.

A review of each of Plaintiffs’ six causes of action reveals that none give rise to an entitlement for relief. As such, the Court should thus dismiss the Complaint.

#### 1. Plaintiffs Sued The Wrong Entities

Plaintiffs cannot meet either the Rule 8 or heightened Rule 9(b) pleading standards as to any claims, for one simple reason: Plaintiffs have named the wrong entities.<sup>9</sup> The named GSK Defendants in the Complaint are (1) GSK PLC, and (2) one of GSK PLC’s subsidiaries, GSK LLC. (*See* Compl. ¶¶ 10, 11.) However, as set forth above in Sections III(D)-(E), neither GSK PLC nor GSK LLC is alleged to have committed any conduct actually directed towards Plaintiffs. Rather, every single individual alleged to have interacted with the Plaintiffs is

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<sup>9</sup> As set forth more fully in Section III, Plaintiffs’ alleged claims arise from the Consultancy Agreement, a contract to which neither GSK PLC nor GSK LLC are signatories.

associated with one of two entirely different GSK subsidiaries: either GSK China, GSK (China) R&D Co. Ltd. (“**GSK China (R&D)**”) or GlaxoSmithKline Pte. Ltd. (“**GSK Singapore**”).

Specifically, as alleged in Plaintiffs’ Complaint:

- The “GSK officials” at the April 15, 2013 meeting at which Plaintiffs were “asked to conduct a background investigation of Shi” (Compl. ¶¶ 49-63) were:
  - Reilly, the General Manager of GSK China; (Compl. ¶ 50.)
  - Zhao, Legal Counsel to GSK China; and (Compl. ¶ 50.)
  - Cahill, an employee of GSK Singapore. (Compl. ¶ 50; *see also* Ex. 9, GSK China Decl. ¶ 10.)
- The employees from whom Humphrey sought additional information (Zhao and Reilly) were Legal Counsel and CEO of GSK China, respectively; (Compl. ¶ 64.)
- The location to which ChinaWhys employee Silvia Feng allegedly traveled to obtain information was the Shanghai office of GSK China; (Compl. ¶ 65.)
- The individuals to whom Humphrey sent a background investigation report (Zhao, Huang, and Cahill) were employees of GSK China, GSK China (R&D) and GSK Singapore; (Compl. ¶ 70.)
- The individuals who requested follow-up investigation work by Humphrey—which Humphrey declined to perform—were legal counsel to GSK China (R&D) (Huang) and Head of Business Development for GSK China (Chang); (Compl. ¶¶ 79, 82-85.)
- The individual who allegedly forwarded Humphrey and a ChinaWhys manager copies of the whistleblower emails was an employee of GSK Singapore (Soon); and (Compl. ¶ 80.)
- Subsequent alleged July 2013 contacts involved only Reilly and his personal assistant (Zheng). (Compl. ¶¶ 86, 89.)

Further, none of this alleged conduct by employees of GSK China and GSK Singapore, even if proven tortious, could be imputed to either of the GSK Defendants in this case. “As a general rule, a parent corporation, like any stockholder, is not normally liable for the wrongful acts or contractual obligations of a subsidiary . . . simply because the parent wholly owns the subsidiary.” *Jean Anderson Hierarchy of Agents v. Allstate Life Ins. Co.*, 2 F. Supp. 2d 688, 691

(E.D. Pa. 1998). Under Pennsylvania law, there is “a strong presumption . . . against piercing the corporate veil. *Germain v. Wisniewski*, No. 15-1297, 2016 WL 4158994, at \*2 (W.D. Pa. Aug. 5, 2016) (quoting *Lumax Indus., Inc. v. Autman*, 669 A.2d 893, 895 (Pa. 1985)). The “formulaic recitation of the elements . . . for piercing the corporate veil” is insufficient to survive a motion to dismiss. *Essex Ins. Co. v. Miles*, No. 10-3598, 2010 WL 5069871, at \*3 (E.D. Pa. Dec. 3, 2010) (allegations that “on information and belief” corporate entity’s owners failed to observe corporate formalities, intermingled funds, used corporate property for personal expenses, left the entity grossly undercapitalized, and used the entity as a façade or alter ego did not meet the *Twombly* pleading standard).

Here, Plaintiffs have not even attempted to allege the elements of a veil piercing claim, making only a bare, conclusory allegation that GSK PLC “had the right to and did exercise control over the actions of” GSK China. (*See* Compl. ¶ 10.) This is insufficient. The allegation that a company is “entirely dominated, operated, and controlled” by another is a “threadbare and conclusory” allegation insufficient to state a claim for veil piercing. *Sunlight Elec. Contracting Co. v. Turchi*, No. 08-5834, 2011 WL 4086077, at \* 17-18 (E.D. Pa. Sept 13, 2011). Where the only allegations against a parent and sister corporation are as to their corporate relationship to the entity that committed the wrongful acts, the complaint must be dismissed as to those defendants. *Jean Anderson Hierarchy of Agents v. Allstate Life Ins. Co.*, 2 F. Supp. 2d at 692; *see also Davis v. Wells Fargo U.S. Bank Nat’l Ass’n*, No. 14-07014, 2015 WL 3555301, at \*4-5 (E.D. Pa. June 8, 2015) (dismissing complaint against corporate parent company for acts committed by its subsidiary).

Simply put, Plaintiffs have sued the wrong corporate entities, and the Complaint should be dismissed in its entirety on this basis alone.

2. Plaintiffs Fail To State A Claim For Violation of 18 U.S.C. § 1962(c) or (d)

Plaintiffs lack standing to bring RICO claims because they do not allege facts supporting a causal link between the GSK Defendants' actions and Plaintiffs' alleged RICO losses. Second, Plaintiffs do not plausibly allege a "pattern" of racketeering activity as required for violation of 18 U.S.C. § 1962(c). Finally, Plaintiffs do not plausibly allege that GSK PLC and GSK LLC entered into an agreement to participate in the affairs of a RICO enterprise, as required under 18 U.S.C. § 1962(d).

i. Plaintiffs Fail To Allege Violation Of § 1962 Proximately Caused Their Damages

Plaintiffs' RICO claims must be dismissed because Plaintiffs do not plausibly allege that a violation of § 1962 proximately caused their damages. Under 18 U.S.C. § 1964(c), a private plaintiff may only bring a civil suit if he or she is "injured in his business or property by reason of a violation of section 1962." 18 U.S.C. § 1964(c). The U.S. Supreme Court has read this requirement strictly: plaintiffs may only recover damages actually and proximately caused by a defendant's RICO violation. *Holmes v. Secs. Investor Prot. Corp.*, 503 U.S. 258, 268-69 (1992). RICO proximate cause is defined by directness: where injury "rests on the independent actions of third and even fourth parties," there is no proximate cause. *Hemi Grp., LLC v. City of New York, N.Y.*, 599 U.S. 1, 15 (2010). Foreseeability—in contrast to many states' common law formulation of proximate cause—is irrelevant. *Id.* It does not matter whether injuries caused by the independent actions of a third party are foreseeable, intended or even desired. *Id.* Rather, the RICO proximate cause requirement "ensures that there are no independent variables that could account for a plaintiff's injuries." *District 1099P*, 784 F. Supp. 2d at 525 (dismissing RICO claims because, among other reasons, defendants' fraudulent statements were not the sole cause of Plaintiffs' injuries).

Here, it was not the alleged actions by GSK LLC, GSK PLC or even GSK China or GSK Singapore that directly caused Plaintiffs' injuries. Rather, Plaintiffs allege their injuries were directly caused by third parties: the Chinese criminal justice system—the Chinese police (Compl. ¶¶ 91-92), prosecutors (Compl. ¶¶ 92-97), and Chinese detention center employees and prison officials (Compl. ¶¶ 99-103). In fact, assuming that Plaintiffs' allegations are true, the actions of the Chinese criminal justice system are arguably fourth party acts, as Plaintiffs allege their “prosecution was procured at the behest of Shi, seeking revenge against them. . . .” (Compl. ¶ 97). Indeed, Plaintiffs do not contest that they committed the violations of law, dating back over many years, that were the cause of their punishment in China.

Plaintiffs make *no* factual allegations that *any* activity by GSK LLC had a causal impact on Plaintiffs, either direct or indirect. Plaintiffs' allegations that GSK PLC's putative refusal to disclose information to British diplomats prolonged Humphrey's and Yu's incarceration is unavailing, as Plaintiffs do not (and cannot) plausibly allege that GSK PLC's alleged statements or refusal to provide information were the *sole* reason that the British government was unsuccessful in securing their early release. (Compl. ¶ 115.)

As alleged, Plaintiffs' injuries simply cannot be considered the “direct” result of action by the GSK Defendants: assuming that Plaintiffs' allegations are true, Plaintiffs' conduct in the investigation incurred the wrath of Shi; Shi purportedly procured Plaintiffs' arrest and prosecution by the Chinese criminal justice system; and inhumane treatment by Chinese authorities injured Plaintiffs. (Compl. ¶¶ 91-104.) Because it was independent actors responding to Plaintiffs' own violations of Chinese law who directly caused Plaintiffs' alleged harm, even accepting their allegations at face value, Plaintiffs cannot claim that their injuries were proximately caused by Defendants.

ii. Plaintiffs Fail To Allege A Pattern Of RICO Activity

“A plaintiff bringing a substantive RICO claim under § 1962(c) must allege ‘(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity.’” *Hlista v. Safeguard Properties, LLC*, 649 F. App’x 217, 221 (3d Cir. 2016) (quoting *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 362 (3d Cir. 2010)). The requirements of § 1962(c) “must be established as to each individual defendant.” *Craig Outdoor Advertising, Inc. v. Viacom Outdoor, Inc.*, 528 F.3d 1001 (8th Cir. 2008).

As the U.S. Supreme Court explained in *H.J. Inc. v. Northwestern Bell Tel. Co.*, a series of racketeering activities only constitutes a RICO “pattern” where the activities are (1) related to each other and (2) amount to or otherwise constitute a threat of continuing racketeering activity. 492 U.S. 229, 240 (1989). Activities are related when they “have the same or similar purposes, results, participants, victims, or methods of commission, or otherwise are interrelated by distinguishing characteristics and are not isolated events.” *Id.* Plaintiffs’ claims regarding the alleged “Drug Bribery and Promotion Enterprise” fail to meet that standard by any definition.

Plaintiffs allege three distinct subsets of conduct within the purported enterprise: (1) the 2012 U.S. Settlement (Compl. ¶¶ 15-22); (2) GSK China’s “Corruption in China” (Compl. ¶¶ 71-78, 116-120); and (3) GSK China’s engagement of Plaintiffs to “conduct a background investigation of [Vivian] Shi” (Compl. ¶¶ 49-70, 79-90). Contrary to the *H.J., Inc.* requirement that the elements of a pattern be “related,” Plaintiffs’ own allegations demonstrate that the purported elements of the alleged RICO enterprise are in fact, entirely unrelated, and do not involve the same or even similar results, participants, victims, or methods of commission. Indeed, timing alone demonstrates the disjointed nature of Plaintiffs’ allegations: there are no allegations involving GSK LLC after the 2012 U.S. Settlement, while GSK China employees are not alleged to have made contact with Plaintiffs prior to mid-2013. (Compl. ¶¶ 15, 50.)

In an attempt to tie these disparate acts together, Plaintiffs argue, without alleging any facts, that each “portion of the enterprise” is connected to the others because all have the “common purpose to maximize and protect GSK profits.” (Compl. ¶ 123.) This bald assertion is insufficient to tie together Plaintiff’s unrelated and disparate allegations.

In *Bonavitacola Elec. Contractor, Inc. v. Boro Developers, Inc.*, plaintiffs alleged conduct over the course of a decade through which the defendant electrical contractor bid for and won several public works projects, in each instance by fraudulently promising to comply with prevailing wage laws and subsequently submitting false certified payroll reports. 87 F. App’x 227, 232 (3d Cir. 2003). Plaintiffs alleged this series of events met the relatedness requirement by virtue of their “similar purpose of procuring electrical construction contracts.” *Id.* The Third Circuit disagreed and affirmed dismissal of these claims, holding that an alleged similar purpose “is not an allegation of common plan.” *Id.* Plaintiffs’ efforts to shoehorn conduct by GSK LLC and GSK PLC into the complaint under the guise of a common purpose of “maximizing profits” similarly fails.

Nor does Plaintiffs’ allegation that they were hired as part of an effort to “cover-up” the alleged enterprise render this series of communications “related” to the activity alleged against GSK LLC. *See The Knit With v. Knitting Fever, Inc.*, 625 F. App’x 27, 38 (3d Cir. 2015) (while a scheme to cover up activity may have “some connection” to that activity, this connection alone is “not sufficient to make two conspiracies part of the same pattern of racketeering”). Indeed, hiring Plaintiffs to conduct a background report into a former employee could not plausibly be part of an effort to “cover-up” any GSK LLC activities, which had already been disclosed to the public as part of its settlement almost a full year before GSK China and GSK Singapore employees allegedly first contacted Plaintiffs. (*See* Exs. 4-5.)

Nor can the “portion” of the alleged racketeering activity purportedly directed towards Plaintiffs stand as a “pattern” on its own. “Predicate acts extending over a few weeks or months and threatening no future criminal conduct do not satisfy” the continuity requirement of *H.J. Inc.* 492 U.S. at 242. All alleged interaction between Plaintiffs and employees of GSK China and GSK Singapore took place during the course of three months. When the alleged pattern of activity takes place over such a short timeframe, and when it is not related to an open-ended pattern of racketeering activity, a claim under 18 U.S.C. § 1962(c) fails. *See Jordan v. Berman*, 792 F. Supp. 380, 385-86 (E.D. Pa. 1992) *partially overruled on other grounds*, 20 F.3d 1250 (3d Cir. 1994) (citing examples of Third Circuit cases holding that “twelve months or less is not a ‘substantial’ period for RICO continuity purposes.”); *Walther v. Patel*, No. 10-706, 2011 WL 382752 at n.105 (E.D. Pa. Feb 4, 2011) (same).

iii. *Plaintiffs’ 1962(d) Claim Fails Because Plaintiffs Have Not Alleged an Agreement*

To plead a cause of action for RICO conspiracy (§ 1962(d)), the complaint “must set forth factual allegations that indicate (1) the period of the conspiracy, (2) its intended purpose, (3) the specific actions taken by the conspirators in furtherance of the conspiracy, (4) agreement to commit predicate acts, and (5) knowledge that the acts agreed upon formed part of a pattern of racketeering activity.” *Ferguson v. Moeller*, No. 2:16-CV-41, 2016 WL 1106609, at \*8 (W.D. Pa. March 22, 2016) (citing *Glessner v. Kenny*, 952 F.2d 702, 714 (3d Cir. 1991)). Plaintiffs must allege facts showing that “each defendant objectively manifested an agreement to participate, directly or indirectly, in the affairs of a RICO enterprise.” *Id.* Plaintiffs’ conclusory allegations do not meet this requirement.

Plaintiffs allege that “[t]he corporate defendants conspired with, inter alia, Mark Reilly and others to promote the red herring investigation of Vivian Shi . . .” (Compl. ¶¶ 140, 141.)

However, Plaintiffs offer no allegations whatsoever to support this statement. They make no claim that any employee of GSK LLC or GSK PLC knew that GSK China and GSK Singapore employees had the objective of “promoting [a] red herring investigation,” let alone that GSK LLC and GSK PLC agreed to further this alleged endeavor for the purpose of “suppress[ing] evidence of GSK’s fraud and bribery in China.” *See Id.* Mere conclusory statements such as these, with “no specific averments regarding . . . agreement to join an alleged conspiracy as to each defendant,” are insufficient to state a cognizable § 1962(d) claim. *Ferguson*, 2016 WL 1106609, at \*9.<sup>10</sup>

3. Plaintiffs’ Claim For Fraud Fails Because Neither GSK Defendant Made Any Allegedly Misleading Statements To Plaintiffs

Plaintiffs’ claim for fraud also fails because the wrong defendants once again were named. Plaintiffs allege that misstatements made to them regarding Shi and the status of a GSK China internal investigation “caused Plaintiffs to agree to conduct the initial investigation, and it was this investigation that led to their arrest, imprisonment, and resulting damages. (Compl. ¶¶ 151, 154, 156.) However, as explained above, there is no allegation that there were any attendees from either GSK PLC or GSK LLC at the April 15, 2013 meeting when the alleged misrepresentations were made. *Id.* at ¶ 50. As there are no such allegations, Plaintiffs’ fraud claims must be dismissed. *Davis*, 2015 WL 3555301 at \*1, 4-5 (dismissing claim for fraud against parent corporation because plaintiff “fails to show how [defendant] was involved in the alleged conduct in any way, other than being the parent company of the company that” is alleged to have caused the injury).

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<sup>10</sup> Further, a number of courts in this circuit have held that a corporation cannot engage in a RICO conspiracy with its own subsidiaries and employees. *See, e.g. Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, No. 07-2860(GEB), 2008 WL 5413105, at \*13 (D.N.J. Dec. 23, 2008) (parent and subsidiary incapable of conspiring, and “an alleged intro-corporate conspiracy comprised solely of a corporation acting in concert with its officers and employees should not be considered as involving separate actors conspiring under the law”); *Castle v. Crouse*, No. 03-5252, 2004 WL 257389, at \*6 (E.D. Pa. Feb.11, 2004) (“a corporate entity cannot conspire with its employees.”).

4. Plaintiffs' Claim For Conspiracy Fails Because Plaintiffs Allege No Malice By Either GSK Defendant

Plaintiffs' claim for civil conspiracy fails for two reasons. First, as with all other claims, there are no factual allegations that either GSK PLC or GSK LLC made any agreement among themselves. Second, Plaintiffs fail to allege any facts from which this Court could plausibly infer the essential element of malice.

To state a claim for conspiracy under Pennsylvania law, plaintiffs must show: (1) a combination of two or more persons acting with a common purpose to do an unlawful act or to do a lawful act, by unlawful means or for an unlawful purpose; (2) an overt act done in pursuance of the common purpose; and (3) actual legal damage. *Morilus v. Countrywide Home Loans, Inc.*, 651 F. Supp. 2d 292, 312 (E.D. Pa. 2008). Additionally, there must be a claim of malice or an intent to injure. *Morilus*, 651 F. Supp. 2d at 313. "Bald assertions that certain actions were malicious are insufficient; it must be alleged that the *sole* purpose of the conspiracy was to injure Plaintiffs." *Id.* (internal quotation and citation omitted) (emphasis in original).

Plaintiffs' claim for civil conspiracy fails because Plaintiffs allege no facts that could allow the court to infer that GSK PLC or GSK LLC harbored any intent to harm Plaintiffs in 2013. Moreover, even if the alleged actions of GSK China or GSK Singapore employees could be imputed to the GSK Defendants (which they cannot), Plaintiffs still fail to allege the essential element of malice against them. Rather, Plaintiffs allege that the GSK Defendants were motivated by their own self-interest: "[the GSK Defendants'] objective in retaining Plaintiffs was to create a dossier on the whistleblower . . . to frame her as a vindictive former employee with a grudge in order to cover-up their conspiracy and obstruct an ongoing investigation into it." (See Compl. ¶ 2.) "[The GSK] Defendants' *true motive* was to use Plaintiffs to discredit the whistleblower and cover up their illegal scheme." (*Id.* at ¶ 1.) (emphasis added). In fact,

Plaintiffs allege facts suggesting GSK China employee Reilly warned Plaintiffs about the fall-out of their report: that Reilly allegedly warned Humphrey that Shi had read the report and would be “coming after” him; and that Reilly informed Humphrey that Reilly planned to leave the country. (*Id.* at ¶¶ 8, 89.) Because the purported conspirators are alleged to have been “guided by personal interests separate from any alleged desire to cause harm to” the plaintiffs, the claim for civil conspiracy must be dismissed. *Morilus*, 651 F. Supp. 2d at 313.

5. Plaintiffs’ Claim For Intentional Infliction Of Emotional Distress Fails To Allege Severe Emotional Distress

First, as previously noted, Plaintiffs’ claims must fail as the GSK Defendants are not alleged to have been involved in any activity directed at or involving Plaintiffs. Second, even if the alleged GSK China employees’ action(s) could be imputed to GSK PLC or GSK LLC (which they cannot), Plaintiffs’ “threadbare legal conclusions” that they suffered “severe emotional distress” do not plausibly state a claim for relief. (Compl. ¶ 162.); *see Robinson v. Family Dollar, Inc.*, No. 14-03189, 2015 WL 3400836, at \*6 (E.D. Pa. May 27, 2015) (allegation that defendants “caused plaintiff to suffer severe emotional distress” are insufficient to state a plausible claim of intentional infliction of emotional distress). Moreover, claims for “both intentional and negligent infliction of emotional distress require a manifestation of physical impairment resulting from the distress.” *Adams v. U.S. Airways Grp., Inc.*, 978 F. Supp. 2d 485, 497 (E.D. Pa. 2013). Plaintiffs make no such allegation, and this claim therefore must be dismissed.

6. Plaintiffs’ Claim For Negligent Infliction Of Emotional Distress Fails Because Plaintiffs’ Cannot Allege Proximate Cause

Plaintiffs’ claim for negligent infliction of emotional distress also fails. First, neither GSK PLC nor GSK LLC is alleged to be involved in or knowledgeable about efforts to engage Plaintiffs to conduct an investigation of Shi. Moreover, it was the intentional actions of the

Chinese government in arresting, prosecuting, and imprisoning defendants that caused Plaintiffs harm, not the actions of any GSK employees, and the claim must therefore be dismissed for lack of proximate cause.

The U.S. District Court for the Middle District of Pennsylvania addressed a similar situation in *Deitrick v. Costa*, No. 4:06-CV-01556, 2015 WL 1606641, at \*9 (M.D. Pa. Apr. 9, 2015). In *Deitrick*, the complaint alleged plaintiffs' injuries resulted from a physical altercation at a police station during which police officers were "detaining and/or assaulting the [p]laintiff." *Id.* Although the *Deitrick* plaintiff sought to causally connect this incident to the defendant, the court dismissed this claim: "even if some as yet unknown act of negligence by defendant . . . is casually related to the police station incident, the intentional conduct of third persons is a superseding cause of the requisite physical impact. Accordingly, the negligent infliction of emotional distress claim should be dismissed." *Id.* at \*9. In this case, Plaintiffs allege they suffered harm at the hands of Chinese authorities while in prison. (*See* Compl. ¶¶ 91-107.) Any causal link to any GSK entity is therefore broken, and Plaintiffs' claim must be dismissed.

#### **E. The Complaint Must Be Dismissed For Failure To Join An Indispensable Party**

Plaintiffs seek to evade the arbitration clause in the Consultancy Agreement by strategically substituting the non-signatory GSK Defendants for the party actually involved in the allegations contained in Plaintiffs' complaint: GSK China. Every allegation in the Complaint revolves around services performed by ChinaWhys for GSK China. GSK China, which has been strategically left unnamed, is a necessary and indispensable party to this proceeding.

Federal Rule of Civil Procedure 12(b)(7) permits dismissal of an action for failure to join a party under Rule 19. Federal Rule of Civil Procedure 19 in turn determines whether a non-joined party is necessary, indispensable, and must be joined. The Court must, therefore, as a

preliminary matter determine whether joinder is compulsory under Rule 19(a). *Dickson v. Murphy*, 202 Fed. Appx. 578, 580 (3d Cir. Pa. 2006). If joinder is required but would divest the court of jurisdiction, the Court must then determine whether the non-joined party is indispensable under Rule 19(b). *Id.*

If the non-joined party is indispensable, the action must be dismissed.

1. GSK China Is A Necessary Party Under Rule 19(a), And Joinder Is Not Feasible

Under Rule 19(a), a non-joined party will be deemed necessary and joinder compulsory under two disjunctive circumstances. First, if “in that party’s absence, the Court cannot afford complete relief among existing parties” (Fed. R. Civ. P. 19(a)(1)(A)), or second, if disposition of the action would impair the non-joined party’s ability to protect its interest or “leave an existing party subject to a substantial risk of incurring double, multiple or otherwise inconsistent obligations because of the interest.” Fed. R. Civ. P. 19(a)(1)(B).

Here, all conduct upon which Plaintiffs predicate their causes of action was allegedly performed by GSK China, not the GSK Defendants. Plaintiffs cannot and do not cite to a single direct contact or encounter with the GSK Defendants. Instead, the Complaint is rife with allegations rooted in the Consultancy Agreement. (*See* Compl. at ¶ 50 (alleging that initial meeting with Plaintiffs took place at GSK China office with GSK China officials); ¶ 65 (alleging that follow-up meeting and collection of investigative material was again attended at and collected from GSK China); ¶ 70 (alleging that Plaintiffs’ Investigation Report was provided to GSK China officials); ¶¶ 71, 72, 113, 116 (alleging bribery and misconduct by GSK China); ¶¶ 79, 82, 83 (alleging that GSK China counsel requested further investigative work from Plaintiffs’); ¶ 84 (alleging that GSK China head of business development also requested investigative work from Plaintiffs).)

As such, neither Plaintiffs nor the GSK Defendants can be afforded complete relief absent GSK China's joinder, as any prospective liability would lie with GSK China, not the GSK Defendants. *See Carl Schroeter GmbH v. Crawford & Co.*, 2009 U.S. Dist. LEXIS 43488 (E.D. Pa. May 19, 2009) ("Plaintiffs' desire to hold [parent] Crawford liable for the acts and omissions of [subsidiary] Crawford Venezuela renders Crawford Venezuela a necessary party to this action"). As a Chinese company which is not alleged to have engaged in any activities in Pennsylvania, (*see* Ex. 9), GSK China is not subject to the personal jurisdiction of the court, and so, joinder is not feasible. Because joinder is not feasible, the Court must proceed to determine whether GSK China is an indispensable party under Rule 19(b), in which case dismissal is the appropriate remedy. *Carl Schroeter GmbH v. Crawford & Co.*, 2009 U.S. Dist. LEXIS 43488 at \*8 (E.D. Pa. May 19, 2009) (dismissal is appropriate where "joinder is not feasible because, for instance, the court lacks personal jurisdiction over the absent party.").

2. GSK China Is An Indispensable Party Under Rule 19(b), Requiring Dismissal Of This Action

The analysis under Rule 19(b) turns upon whether a Court, "in equity and good conscience," should allow the litigation to proceed without the non-joined parties. Fed. R. Civ. P. 19(b). Factors to be weighed in making this determination include: "[F]irst, to what extent a judgment rendered in the person's absence might be prejudicial to the person or those already parties; second, the extent to which, by protective provisions in the judgment, by the shaping of relief, or other measures, the prejudice can be lessened or avoided; third, whether a judgment rendered in the person's absence will be adequate; fourth, whether the plaintiff will have an adequate remedy if the action is dismissed for nonjoinder." Fed. R. Civ. P. 19(b)(1)-(4).

Applying these tests to the present case compels the conclusion that GSK China is indispensable. A judgment rendered in GSK China's absence would prejudice not only Plaintiffs

and the GSK Defendants, as discussed *supra*, but GSK China itself, as such a judgment would be, in effect, entirely “hollow” as to it. *Jurimex Kommerz Transit G.m.b.H. v. Case Corp.*, 201 F.R.D. 337, 340-341 (D. Del. 2001), *aff’d* 2003 U.S. App. LEXIS 7690 (3d Cir. Apr. 23, 2003) (“A judgment in defendant's favor would not be ‘adequate’ because Plaintiffs could subsequently sue the [absent] Subsidiaries in a different forum based on essentially the same facts, while a judgment in Plaintiffs' favor may be ‘hollow’ because the proper defendant was never joined”).

In *Jurimex*, the plaintiff, an Austrian corporation, sought to avail itself of U.S. courts by asserting contract and tort claims against a U.S. parent for conduct allegedly committed by the parent’s foreign subsidiaries. Finding that “most of [p]laintiffs’ interactions and negotiations regarding the Transaction were with the Subsidiaries and not with [d]efendant,” the court deemed the absent subsidiaries indispensable. *Id.* at 340.

This Court reached the same conclusion in *Carl Schroeter GmbH v. Crawford & Co.* when presented with similarly misplaced claims strategically asserted, like those brought by Plaintiffs here, against a domestic parent in lieu of its foreign subsidiary. No. 09-946, 2009 U.S. Dist. LEXIS 43488, 11-12 (E.D. Pa. May 19, 2009) (noting that “when a defendant is sued solely in connection with its subsidiary's conduct, the subsidiary is a necessary and indispensable party” and accordingly dismissing complaint where “foreign plaintiffs [sued] American corporate defendant, seeking to hold that defendant liable for its [absent] foreign subsidiary’s conduct.”).

Significantly, Plaintiffs have an adequate remedy and forum should the Court dismiss this litigation for non-joinder and, more specifically, one to which they have agreed. The Consultancy Agreement provides for the arbitration of “all disputes arising out of or in connection” with the Agreement. (*See* Ex. 1, Consultancy Agreement § 11.) Arbitration would

allow all relevant parties to rightfully adjudicate their respective claims, and dismissal is thus warranted here.

Thus, this Court should dismiss this action for non-joinder of GSK China, a necessary and indispensable party.

**F. Causes Of Action III (Fraud), IV (Intentional Infliction Of Emotional Distress) And V (Negligent Inflict of Emotional Distress) Are Barred By Pennsylvania's Statute Of Limitations.**

In the Commonwealth of Pennsylvania, “[t]he limitations period for any claim begins to run ‘from the time the cause of action accrue[s].’” *Beasley v. Young, Ricchiti, Caldwell & Heller, LLC*, No. 2873 EDA 2012, 2013 WL 11250696, at \*5 (Pa. Sup. Ct. Nov. 4, 2013) (*citing* 42 Pa. C.S.A. §§ 5502(a)). Specifically, “a cause of action accrues when the plaintiff could have first maintained the action to a successful conclusion. . . . [T]he statute of limitations begins to run as soon as the right to institute and maintain a suit arises. . . . Once a cause of action has accrued and the prescribed statutory period has run, an injured party is barred from bringing his cause of action.” *Fine v. Checcio*, 870 A.2d 850, 857 (Pa. 2005).

Pursuant to 42 Pa. C.S.A. §§ 5524(7), claims concerning fraud, intentional infliction of emotional distress and negligent infliction of emotional distress are governed by a two-year statute of limitations. The Complaint alleges that the GSK Defendants made false representations and intentionally misled Plaintiffs between April and July 2013 (*See* Compl. ¶¶ 49, 56, 64-65, 67, 70, 79-81, 84, 86, 91, 150-170.) Therefore, because the Complaint was served on the GSK Defendants in November 2016, which was more than three years from the latest date at which the alleged causes of action began to accrue, counts III, IV and V are time-barred. As the statutory framework in Pennsylvania clearly addresses, Plaintiffs are not entitled to toll their claims merely because of Humphrey’s and Yu’s incarceration. *See* 42 Pa. C.S.A. § 5533(a) (providing that “imprisonment does not extend the time limited by this subchapter for the

commencement of a matter.”); *see also Johnson v. Romig*, No. 11-02052, 2013 WL 6916428, at \*2 (Pa. Dec. 19, 2013). Accordingly, Counts III, IV and V in the Complaint should be dismissed with prejudice.

### **G. Plaintiffs Lack Standing To Assert Their Purported RICO Claims**

Section 1964(c) identifies four factors that must be satisfied to establish standing for a civil RICO claim: (1) the plaintiff must be a “person” (2) who sustains injury (3) to its “business or property” (4) “by reason of” the defendant’s violation of § 1962. Thus, a RICO “plaintiff only has standing if, and can only recover to the extent that, he has been injured in his business or property by the conduct constituting the violation.” *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985). Critically, RICO does not encompass foreign injuries to business or property. In a very recent opinion, *RJR Nabisco v. European Community, et al*, 136 S. Ct. 2090 (2016), the Court held that “a private RICO plaintiff... must allege and prove a *domestic* injury to its business or property.” *Id.* at 2106 (emphasis in original). Thus, RICO “does not allow recovery for foreign injuries.” *Id.* at 2111. As these are the only injuries alleged by Plaintiffs, their RICO claims must be dismissed.

The only injuries to business or property claimed by Plaintiffs in connection with their RICO claims are that “Plaintiffs’ business was destroyed and their prospective business ventures eviscerated” (Compl. ¶132) and that they have allegedly been “put out of business.” (Compl. ¶145.)<sup>11</sup> Plaintiffs allege that their business, ChinaWhys, had numerous clients in the U.S., but they fail to mention that it only had offices in China. (*See* Exs. 10-13.)<sup>12</sup> Although

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<sup>11</sup> Plaintiffs’ allegations of personal injuries suffered while imprisoned are not cognizable under RICO. *See, e.g., Magnum v. Archdiocese of Philadelphia*, 253 F. App’x 224, 227 (3d Cir. 2007) (“[P]hysical or emotional harm to a person is not property under civil RICO. Similarly, losses which flow from personal injuries are not property under RICO.”); *Genty v. Resolution Trust Corp.*, 937 F.2d 899, 918–19 (3d Cir. 1991) (“RICO plaintiffs may recover damages for harm to business and property only, not physical and emotional injuries[.]”).

<sup>12</sup> *See* discussion *supra* at Section III(C).

Plaintiffs attempt to manufacture a U.S. connection by alleging that Humphrey had communications with employees of GSK China while he was travelling in the U.S., they make no claim that Humphrey’s travel had anything to do with the GSK engagement—because it did not—and the communications themselves exclusively concerned ChinaWhys’ activities in China. (Compl. ¶ 83 (alleged call between Humphrey and GSK China (R&D) counsel concerning Chinese Public Security Bureau research); Compl. ¶ 84 (alleged request from GSK China head of business development concerning research into various Chinese government entities)). In short, Plaintiffs make no allegation that ChinaWhys performed any work outside of China relating to its engagement by GSK China, and none of the communications through which Plaintiffs maintain they were deceived were made by employees of GSK LLC, the only U.S. entity involved on either side of this litigation.

Given these facts, any injury suffered by ChinaWhys is indisputably foreign. Although the Court in *RJR Nabisco* did not address the definition of a “foreign injury,” it explained the question before it as “whether the court has authority to recognize a cause of action for injury *suffered overseas*” (*id.* at 2109) (emphasis added), and concluded that “damages claims [which] rest entirely on *injury suffered abroad* ... must be dismissed.” (*id.* at 2111) (emphasis added). Here, ChinaWhys is a Chinese company that is alleged to have been damaged when its principals, who lived and worked in China, were imprisoned in China after they performed work in China at the request of GSK China, another China company. Plaintiffs claim that ChinaWhys had U.S. clients is irrelevant—those clients had no involvement whatsoever in the events alleged in the Complaint, nor are their locations relevant to determining where ChinaWhys was injured—only ChinaWhys’ location is relevant to answering this question.

The handful of cases to consider the definition of a “foreign injury” since *RJR Nabisco* support this conclusion. In *Bascunan v. Els*, 2016 WL 5475998 (S.D.N.Y. Sept 28, 2016), the Court concluded that losses suffered by a Chilean plaintiff were foreign losses, despite the fact that a number of the underlying allegations, such as physical misappropriation of bearer shares from a bank safety deposit box, had occurred in New York. The *Bascunan* court also concluded that injuries suffered by a corporate plaintiff are not “domestic” when the plaintiff is incorporated in a foreign country and does not have a U.S. principal place of business. *Id.* at \*6 (“[If] the Corporate Plaintiffs suffered economic injury, they too, suffered their injuries abroad because each was incorporated in the British Virgin Islands or Chile, and the Amended Complaint has not alleged that their principal place of business is in the U.S.”)) Notably, either approach to determining the location of injury that was considered by the *Bascunan* court—(i) location of the injury or (ii) location of the conduct leading to the injury—would lead in the present case to the conclusion that any injury suffered by ChinaWhys is foreign, for ChinaWhys was located in China and only alleges injury arising from conduct occurring in China.

In *Union Commercial Services Ltd v. FCA International*, 2016 WL 6650399 (E.D. Mich. Nov. 10, 2016), the court applied a “substantial effects” test, derived from antitrust law, to determine whether an injury was domestic under *RJR Nabisco*. Although the plaintiff alleged that it had a business office and bank accounts in Florida, and that funds relating to the alleged RICO violations had been transferred through them, the court concluded that “defendants’ alleged conduct was directed at, and any effects were felt by, plaintiff’s business or property interests outside of the U.S.” *Id.* at \*5. Thus, despite plaintiffs’ allegations of U.S. connections—allegations with an actual connection to the underlying claims, unlike the ChinaWhys allegations here—the court dismissed the complaint for failure to allege a domestic

injury, based upon the foreign nexus of the underlying injury. Similarly, in *Exeed Industries v. Younis*, 2016 WL 6599949 (N.D. Ill. Nov. 8, 2016), the court dismissed RICO claims alleging that U.S. suppliers of a United Arab Emirates company were duped into paying fraudulent invoices whose proceeds were used by the defendants to finance U.S. land purchases. The court concluded that “the few cases to address the issue of domestic injury post-*RJR Nabisco* have interpreted it to mean that an injury arises where it was initially suffered by the plaintiff,” (*id.* at \*3) and that “the fact that a large number of Plaintiff’s suppliers have offices in the U.S. does not speak to where the injury was felt by the Plaintiffs themselves—that question can only be answered by looking to the Plaintiffs’ business operations in the UAE.” *Id.*

Here, ChinaWhys is a Chinese company, and its only allegations of conduct allegedly directed against it involve actions by GSK China in China. Any injuries that ChinaWhys has suffered are foreign, and Plaintiffs’ RICO claims must therefore be dismissed.

## **V. CONCLUSION**

For the reasons set forth above, the GSK Defendants respectfully request that the Court compel arbitration pursuant to the Consultancy Agreement, and stay all proceedings pending conclusion of such arbitration. In the alternative, for the reasons set forth herein, the GSK Defendants request that the Court dismiss the entirety of Plaintiffs complaint.

Dated: January 16, 2017

Respectfully submitted,

/s/ Jayne A. Risk

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and Specially Appearing Defendant  
GlaxoSmithKline plc.*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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PETER HUMPHREY, YU YINGZENG, and  
CHINAWHYS COMPANY LTD,

Plaintiffs,

v.

GLAXOSMITHKLINE PLC and  
GLAXOSMITHKLINE LLC,

Defendants.

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Civil Action No.: 2:16-CV-5924

**ORDER**

AND NOW, this \_\_\_\_ day of \_\_\_\_\_, 2017, upon consideration of Defendants GlaxoSmithKline PLC and GlaxoSmithKline LLC's Motion to Compel Arbitration or, in the Alternative, Motion to Dismiss the Complaint, it is hereby ORDERED that the motion is GRANTED. The above-referenced matter is referred to arbitration before the China International Economic and Trade Arbitration Commission. All further proceedings in this matter are STAYED pending disposition of arbitration.

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HON. NITZA I. QUIÑONES-ALEJANDRO  
United States District Judge

**CERTIFICATE OF SERVICE**

I certify that on January 16, 2017 , I caused a copy of the foregoing Motion to Compel Arbitration or, in the Alternative, Motion to Dismiss the Complaint, along with the accompanying Memorandum of Law and exhibits thereto, to be served on the following individuals via the means specified below:

**Via the Court's CM/ECF System:**

Joan D. Gallagher  
**GALLAGHER & TURCHI**  
1600 Market Street, Suite 1320  
Philadelphia, PA 19103  
[joanie@gallagher-law.com](mailto:joanie@gallagher-law.com)

John T. Zach  
Philip Bowman  
**BOIES, SCHILLER & FLEXNER LLP**  
575 Lexington Avenue  
7TH Floor  
New York, NY 10022

By: /s/ Jayne A. Risk  
Jayne A. Risk

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

PETER HUMPHREY, YU YINGZENG, and  
CHINAWHYS COMPANY LTD,

Plaintiffs,

v.

GLAXOSMITHKLINE PLC and  
GLAXOSMITHKLINE LLC,

Defendants.

Civil Action No.: 2:16-CV-5924

**DECLARATION OF JAYNE ANDERSON RISK IN  
SUPPORT OF DEFENDANTS' MOTION TO COMPEL  
ARBITRATION, OR, IN THE ALTERNATIVE,  
MOTION TO DISMISS THE COMPLAINT**

JAYNE ANDERSON RISK, an attorney duly admitted to practice law in the U.S. District Court for the Eastern District of Pennsylvania, affirms, under penalty of perjury, the following to be true:

1. I am a member in good standing of this Court, and a partner in the law firm of DLA Piper LLP (US), counsel to GlaxoSmithKline plc ("**GSK PLC**") and GlaxoSmithKline LLC ("**GlaxoSmithKline LLC**") (together, the "**GSK Defendants**") in the above-captioned matter. I submit this Declaration in support of Defendants' Motion To Compel Arbitration, Or, In The Alternative, Motion To Dismiss The Complaint.

2. Attached hereto as Exhibit 1 is a true and correct copy of a consultancy agreement dated April 25, 2013 including Appendix A ("**Consultancy Agreement**") entered into by GlaxoSmithKline (China) Investment Co. Ltd. ("**GSK China**") and ChinaWhys (Shanghai) Consulting Co. Ltd. ("**ChinaWhys (Shanghai)**").

4. Attached hereto as Exhibit 2 is a true and correct screenshot taken on January 14, 2017 of an August 27, 2013 article published by *China Daily USA* which is publicly available at [http://usa.chinadaily.com.cn/china/2013-08/27/content\\_16922439.htm](http://usa.chinadaily.com.cn/china/2013-08/27/content_16922439.htm).

5. Attached hereto as Exhibit 3 is a true and correct screenshot taken on December 7, 2016 of an article in *The Fraud Examiner* dated May 2013 entitled “How Fraud Investigation Just Got Harder in China” which is publicly available at <http://www.acfe.com/fraud-examiner.aspx?id=4294978054>.

6. Attached hereto as Exhibit 4 is a true and correct screenshot taken on January 14, 2017 of the U.S. Department of Justice’s July 2, 2012 press release which is publicly available at <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report>.

7. Attached hereto as Exhibit 5 is a true and correct screenshot taken of the Department of Justice website on January 14, 2017 of the Corporate Integrity Agreement dated July 2, 2012 which is publicly available at <https://www.justice.gov/sites/default/files/opa/legacy/2012/07/02/hhs-oig-corp-integrity-agreement.pdf>.

8. Attached hereto as Exhibit 6 is a true and correct screenshot taken on January 14, 2017 of a GSK press release dated September 19, 2014 titled “GSK China Investigation Outcome” which is publicly available at <http://www.gsk.com/en-gb/media/press-releases/2014/gsk-china-investigation-outcome/>.

9. Attached hereto as Exhibit 7 is a true and correct screenshot taken on January 14, 2017 of a U.S. Securities and Exchange Commission (“U.S. S.E.C.”) press release which is publicly available at <https://www.sec.gov/litigation/admin/2016/34-79005-s.pdf>.

10. Attached hereto as Exhibit 8 is a true and correct copy of a U.S. SEC administrative proceeding order dated September 30, 2016 *In the Matter of GlaxoSmithKline pc* (File No. 3-17606) which is publicly available at <https://www.sec.gov/litigation/admin/2016/34-79005.pdf>.

11. Attached hereto as Exhibit 9 is a Declaration of GSK China.

12. Attached hereto as Exhibit 10 is a true and correct screenshot taken on January 14, 2017 of a page from ChinaWhys' website entitled "An International Business Risk Advisory Firm with Eyes in China" which is publicly available at <http://chinawhys.com/aboutus.htm>.

13. Attached hereto as Exhibit 11 is a true and correct screenshot taken on December 7, 2016 of Peter Humphrey's biography on ChinaWhys' website which is publicly available at <http://chinawhys.com/peter.htm>.

14. Attached hereto as Exhibit 12 is a true and correct screenshot taken on December 7, 2016 of Yingzeng Yu's biography on ChinaWhys' website which is publicly available at <http://chinawhys.com/yingzeng.htm>.

17. Attached hereto as Exhibit 13 is the Declaration of GSK PLC

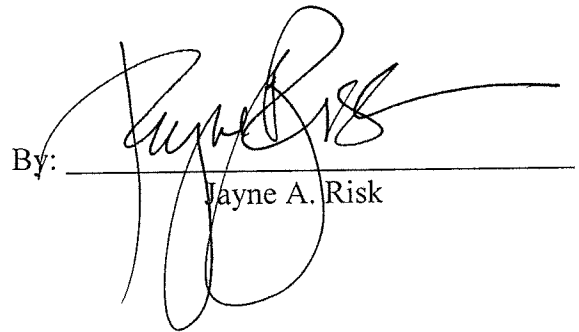
18. Attached hereto as Exhibit 14 is the Declaration of GSK LLC

19. Attached hereto as Exhibit 15 is a true and correct screenshot taken on January 14, 2017 of an article on Lexology titled "*Conviction of Private Investigators in China Further Complicates Anti-Corruption Compliance Efforts*" which is publicly available at [www.lexology.com/library/detail.aspx?g=dbb77b00-ce7f-4606-8b65-f0148297d6b6](http://www.lexology.com/library/detail.aspx?g=dbb77b00-ce7f-4606-8b65-f0148297d6b6).

20. Attached hereto as Exhibit 16 is a true and correct screenshot taken on January 14, 2017 of an article published by CCTV.com (English) on August 27, 2013 titled "Foreign

Couple Arrested for Selling Personal Information” which is publicly available at <http://english.cntv.cn/program/newshour/20130827/102867.shtml>.

Dated: Philadelphia, Pennsylvania  
January 16, 2017

By:   
Jayne A. Risk

To: ChinaWhys (Shanghai) Consulting Co Ltd (in Chinese 摄连咨询(上海)有限公司)

Address: 35-107 CITIC Square, 1168 Nanjing West Road, Shanghai 200041, China

Date: April 25, 2013

Dear Mr. Peter Humphrey,

**CONSULTANCY AGREEMENT (this “Agreement”)**

We set out below the terms on which you have agreed to provide certain consultancy services to us with respect to the proposed investigation and inquiry activities to be detailed in the proposal for Project Scorpion (“the Project”).

**1. SERVICES**

- 1.1 We hereby engage you to provide the following services (“the Consultancy Services”) to us and you agree to provide the Consultancy Services to us using due care and skill. The scope of Consultancy Services is detailed in the Project Proposal as attached in Appendix A hereto.
- 1.2 You will provide the Consultancy Services to us at such times and at such locations as we shall agree from time to time. You shall ensure that when carrying out the Services at a GSK site, you conform with all GSK’s policies and procedures with regard to working conditions, safety, security and similar matters and agree at all times during the performance of the Services to comply with such reasonable requirements as may be notified to you from time to time.
- 1.3 You will only contact third parties in pursuance of the Consultancy Services after our express written consent that you may do so to enable us to put in place a Confidentiality Agreement with that third party if we require it. Where approval has been given to contact any third party, you will agree in advance with us what information you may disclose about the Project and our business to that third party. We may specify that you are not permitted to disclose that you are working for GlaxoSmithKline when you make any authorised contact with third parties and you agree to respect any such requirement absolutely.
- 1.4 You will at our request produce and submit to us a final presentation and written report of all recommendations and findings arising out of the Consultancy Services immediately prior to the termination of this Agreement.

- 1.5 You represent that you are under no obligation which is inconsistent with this Agreement and that you will not enter into any agreement with a third party, the terms of which may be inconsistent with this Agreement.
- 1.6 You shall carry out the Consulting Services always in a lawful and ethical manner. The term 'ethical' used in this policy means: in compliance with all laws, regulations, legal and professional guidelines, and in a manner not likely to result in harm to GSK's reputation or image.

**2. COMMENCEMENT DATE**

This Agreement will commence on the signature by the authorized representative of each party and will continue, subject to the provisions of Clause 8, until the Consulting Services is completed.

**3. FEES AND EXPENSES**

- 3.1 For Services actually rendered hereunder, we agree to pay you a fixed sum of **[RMB 220,000]** (exclusive any applicable business Tax or VAT) ("Service Fees"). Fifty per cent (50%) of the Service Fees will be payable within thirty (30) days of the date of your invoice, which you will submit to us during the last week of each calendar month. The payment term for subsequent invoice is 60 days. You will provide a detailed summary of the Consultancy Services provided and of the hours worked for the work period invoiced.
- 3.2 We will pay your reasonable round-trip travelling and living expenses from your home to the consulting site while travelling at our request subject to the provision of proper receipts. Claims for travelling and living expenses shall be submitted by you at the end of each trip taken during which this Agreement remains in effect, and we will pay such expenses after receipt and approval thereof. Where any travel will require you to travel to another country than your normal country of residence, express written consent from us will be required before incurring such expenditure. These out-of-pockets shall not exceed the equivalent of 15% of Service Fees.
- 3.3 The payments referred to in Clauses 3.1 and 3.2 are full and complete compensation for all obligations assumed under this Agreement and for all inventions, improvements, patent rights or other Intellectual Property Rights (as defined in Clause 5 below) assigned under this Agreement.

- 3.4 You will be responsible for all costs in respect of the fees paid under this Agreement including, without limitation, the payment for and provision of all benefits and national insurance contributions and the payment of all employment and income related taxes. You agree to indemnify us in respect of any claims by the relevant authorities against us in respect of employment or income tax or national insurance or any other costs relating to the provision of the Services hereunder.

**4. CONFIDENTIALITY**

- 4.1. You agree to treat as secret and confidential and will not at any time nor for any reason disclose or permit to be disclosed to any person (except in accordance with Clause 1.3 above) or otherwise make use of or permit to be made use of, any information relating to the Products(s) / Project(s) whether disclosed by us or generated by you or to any technology, technical processes, business affairs, patents or finances or any such information relating to us or to any Affiliate, supplier, customer or client of ours ("Information") where knowledge or details of the Information was received, acquired or developed by you during the period of this Agreement.
- 4.2 Upon termination of your appointment under this Agreement for whatever reason, you shall forthwith deliver up to us all Information which may be in your possession, custody or control and which are our or our Affiliates' property or which otherwise relate in any way to the business or affairs of us or our Affiliates and no copies of the same or any part thereof will be retained by you. Such return will not affect your obligations under Clause 4.1.
- 4.3 The above obligations of confidentiality and non-use shall not apply to information and data which you can show were already known to you, information and data which are or become part of the public domain through no fault of your own and information and data which are given to you by a third party who has a right to do so.
- 4.4 The provisions of this Clause 4 will survive termination of this Agreement.
- 4.5 Further, the Confidentiality Agreement already signed between us shall be deemed to form part of this Agreement.

**5. INTELLECTUAL PROPERTY RIGHTS**

- 5.1 You shall disclose promptly to us any inventions, improvements, derivative works or alternatives made or conceived by you, either alone or jointly with others, in the course of or as a result of the work done hereunder, or as a consequence of confidential information supplied for the purposes hereof, directly or indirectly, by us or our affiliates or agents (which, for the avoidance of doubt, shall include their directors, officers or employees). You hereby assign to us or to any Affiliates of ours, to the extent permitted by law, all Intellectual Property Rights in any work generated by you on or after the commencement of this Agreement and pursuant to this Agreement and you agree to provide all necessary assistance as we may consider necessary in order to assign such Intellectual Property Rights to us or any Affiliate of ours, including, but not limited to, the execution of such documents as may be required to file applications for and obtain Intellectual Property Rights in any country in our or our Affiliates' name.
- 5.2 The term "Intellectual Property Rights" means all patents, trademarks, service marks, designs (whether or not registered) and applications therefor, present and future copyright, database rights, trade secrets, domain names, rights in know-how and other rights of confidence and all other rights of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world.
- 5.3 You hereby grant (and shall procure the grant of) to us or to any of our Affiliates at our option a non-exclusive, royalty-free, world-wide, perpetual, irrevocable, assignable licence (with the right to licence freely) of all Intellectual Property Rights created prior to the commencement of this Agreement which are necessary for the receipt and use of each deliverable arising out of the Consultancy Services.

**6. NOTICES**

- 6.1 Any notices, payments or statements to be made under this Agreement shall be made to you at the address to which this Agreement is directed and to Mr. Peter Humphrey at the ChinaWhys address stated above, or at such other address later designated in writing by the other party for such purposes.

- 6.2 Any notice required by this Agreement to be given by either of us to the other will be in writing and will be served by sending it by registered mail, recorded delivery courier or delivered by hand and any receipt issued by the postal authorities or by the courier or on hand delivery will be inclusive evidence of the fact and the date of posting of any such notice.

**7. INDEPENDENT CONTRACTOR RELATIONSHIP**

You agree that you will be serving under this Agreement as an independent contractor and that the relationship of employer and employee shall not exist between you and ourselves at any time as a result of the arrangements contemplated by this Agreement.

**8. TERMINATION AND SURVIVAL TERMS**

- 8.1 We may by giving notice in writing to you terminate this Agreement in the event that you:

8.1.1 act in breach of any of the terms of this Agreement which in the case of a breach capable of remedy, has not been remedied by you within ten (10) days of receipt by you of a notice from us specifying the breach and requiring its remedy;

8.1.2 are judged in our sole discretion, to be incompetent or negligent in the provision of the Consultancy Services.

- 8.2 The Agreement may be cancelled at any time by us for any reason whatsoever, by giving You notice in writing.

- 8.3 Upon termination, You will be compensated for the Consulting Services actually performed and reimbursed for expenses actually and reasonably or non-cancellable in accordance with the terms hereof.

- 8.4 Clauses 4, 5, 6, 9, 10, 11 and 12 of this Agreement shall survive the expiration or termination of this Agreement.

**9. DATA PROTECTION**

You consent to us holding and processing, both manually and electronically, any data it collects regarding you for the purpose of administering and managing its business and for compliance with applicable procedures, laws and regulations.

**10. SYSTEMS**

You shall ensure that any deliverables provided to us under this Agreement shall:

- 10.1 be provided in a mutually agreed electronic format;
- 10.2 be free from defects, disabling codes, computer viruses, worms, logic bombs, Trojan horses and other information technology contaminants or unauthorised computer code and have been tested to be so; and
- 10.3 comply and function substantially in accordance with their related user documentation.

**11. GOVERNING LAW AND DISPUTE RESOLUTION**

This Agreement shall be governed in all respects by the laws of the People's Republic of China. All disputes arising out of or in connection with this Agreement shall be settled through friendly consultation between both parties. In case no settlement can be reached, either Party may submit the dispute to the China International Economic and Trade Arbitration Commission ("CIETAC") in Beijing for arbitration in accordance with the CIETAC rules of arbitration then in effect. The arbitration award shall be final and binding on the Parties.

**12. SEVERANCE**

Each clause of this Agreement is a distinct and severable clause and if any clause is deemed illegal, void or unenforceable, the validity, legality, or enforceability of any other clause or portion of this Agreement shall not be affected thereby.

**13. CONFLICT OF INTEREST**

While providing Services under this Agreement you agree that you shall not be engaged in or concerned with either directly or indirectly any other business or profession which either competes with ours or might otherwise cause a conflict of interest without our prior written consent. If in any doubt as to whether a conflict of interest might exist you should immediately discuss the matter with [Mr. Mark Reilly] before accepting such position.

**14. WAIVER**

The failure of a party in any instance to insist on the strict performance of the terms of this Agreement shall not be construed to be a waiver or relinquishment of any of the terms of this Agreement either at the time of the party's failure to insist upon strict performance or at any subsequent time.

**15. ENTIRE AGREEMENT**

15.1 This Agreement constitutes the whole and only agreement between the parties relating to the Services and any previous agreement will be deemed to have terminated. Each party acknowledges that in entering into this Agreement it is not relying upon any pre-contractual statement which is not attached to this Agreement. Except in the case of fraud, no party shall have any right of action against any other party to this Agreement arising out of or in connection with any pre-contractual statement except to the extent that it is repeated in this Agreement.

15.2 For the purposes of this clause, "**pre-contractual statement**" means any draft, agreement, undertaking, representation, warranty, promise, assurance or arrangement of any nature whatsoever, whether or not in writing, relating to the subject matter of this Agreement made or given by any person at any time prior to the date of this Agreement.

**16. FORCE MAJEURE**

16.1 Neither party shall be liable for any delay or failure in performing any of its obligations under this Agreement if the delay or failure results from events or circumstances beyond its reasonable control (including without limitation any acts or restraints of governments or public authorities, war, revolution, riot or civil commotion, acts of God or fire but excluding strikes and lockouts) ("Force Majeure") provided that the party so affected shall send to the other party a written notice within three (3) days of becoming aware of such Force Majeure giving full particulars thereof including the date of first occurrence, the circumstances giving rise to it and an indication of the duration of such circumstances.

16.2 If the period of delay or failure extends for sixty (60) days or more from the date of notification of the Force Majeure event to the other party, either party shall have the right to terminate the Agreement forthwith by written notice.

**17. LIABILITY**

17.1 You shall not be liable for any loss, damage or delay suffered by us insofar as such loss, damage or delay is directly attributable to instruction given or actions undertaken by us or on our behalf.

17.2 You shall indemnify us, our Affiliates and any servant or agent of ours against:

17.2.1 any loss or damage caused to any property of ours, our Affiliates or our servants or agents or any physical injury (including injury resulting in death) sustained by any servant or agent of ours by reason of any negligent or wilful act or omission of you at any time during the performance of the Consultancy Services; or

17.2.2 any claim demand or liability made against or incurred by us, our Affiliates or our servants or agents in respect of:

(i) any loss of or damage to any property of yours or injury (including injury resulting in death) sustained by you in the provision of the Consultancy Services unless such loss, damage or injury is caused by the negligent act or omission of us, our Affiliates or any of our servants or agents;

(ii) any loss, damage or injury (including injury resulting in death) sustained by any third party in the provision of the Consultancy Services in consequence of any negligence or wilful act or omission of you; or

(iii) the receipt or use of any Intellectual Property Rights assigned or licensed to us or any of our Affiliates under Clause 5 which infringes the Intellectual Property Rights of a third party.

If the foregoing terms and conditions are acceptable to you, we would be grateful if you could sign and return the enclosed duplicate copy of this Agreement.

**18. ANTI-BRIBERY AND CORRUPTION**

- 18.1 You acknowledge that you have received and read the 'Prevention of Corruption – Third Party Guidelines' (either in hard copy in Appendix or at <http://www.gsk.com/policies/Prevention-of-Corruption-Third-Party-Guidelines.pdf>) and agree to perform your obligations under the Agreement in accordance with the principles set out therein.
- 18.2 You shall comply fully at all time with all applicable laws and regulations, including but not limited to applicable anti-corruption laws, of the territory in which you conduct business with GSK.
- 18.3 You agree that you have not, and covenant that you will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorise, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting you or GSK in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery.
- 18.4 You shall not contact, or otherwise meet knowingly meet with any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of GSK and, when requested by GSK, only in the presence of a GSK designated representative.
- 18.5 For the purpose of this Agreement "Government Official" means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organisation such as the World Bank or United Nations; (e) any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office; who, when such Government Official is acting in an official capacity, or in an official decision making role, has responsibility for performing regulatory inspections, government authorisations or licenses, or otherwise has the capacity to take decisions with the potential to affect GSK business.
- 18.6 You represent that except as disclosed to GSK in writing prior to the commencement of this Agreement, you have not been convicted of or pleaded guilty to a criminal offence, including one involving fraud or corruption, that you are not now, to the best of your knowledge, the subject of any government investigation for such offenses, and that you are not now listed by any government agency as debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs.

- 18.7 You represent and warrant that except as disclosed to GSK in writing prior to the commencement of this Agreement: (1) you do not have any interest which directly or indirectly conflicts with your proper and ethical performance of this Agreement; and (2) you shall maintain arm's length relations with all third parties with which you deal for or on behalf of GSK in performance of this Agreement.
- 18.8 GSK shall have the right during the terms of this Agreement to conduct an investigation and audit of your activities under this Agreement to monitor compliance with the terms of this Agreement. You shall cooperate fully with such investigation or audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of GSK.
- 18.9 You shall ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on your books and records and each document upon which entries such books and records are based is complete and accurate in all material respects. You must maintain a system of internal accounting controls reasonably designed to ensure that you maintain no off-the-books accounts.
- 18.10 You agree that in the event that GSK believes that there has been a possible violation of the terms of this Agreement, GSK may make full disclosure of such belief and related information at any time and for any reason to any competent government bodies and its agencies, and to whomsoever GSK determines in good faith has a legitimate need to know.
- 18.11 GSK shall be entitled to terminate this Agreement with immediately on written notice to you, if you fail to perform your obligations in accordance with this Clause 18. You shall have no claim against GSK for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Clause 18. To the extent (and only to the extent) that the laws of the territory provide for any such compensation to be paid to you upon the termination of this Agreement, you hereby expressly agree (to the extent possible under the laws of the territory) to waive or to repay to GSK any such compensation or indemnity.

**19. Adverse Event Reporting**

- 19.1 GSK is required by law to report adverse events associated with GSK products to the relevant authorities. If in the course of providing the Services you receives a report of an adverse event related to a GSK product, you will attempt to obtain the reporter's name and contact details and the name and formulation of the product involved. You will either report the information to a member of GSK staff or to GSK using the contact details set out below within 24 hours. You will inform the reporter that a representative from GSK may contact them to request additional information. If the reporter is a patient or consumer, you will suggest that they should consult their doctor.

For reports of adverse events associated with medicinal products:

Tel: 400-183-3383 or 800-820-3383

- 19.2 If GSK identifies any reports of adverse events associated with GSK products in materials provided by you for the Consultancy Services, GSK will report such adverse events to the relevant authorities in accordance with its standard procedures. In this case, you agree to co-operate with, and provide further information to, GSK safety staff, within 24 hours, as requested.

Yours faithfully

For and on behalf of

[GLAXOSMITHKLINE (CHINA) INVESTMENT CO., LIMITED]

I agree to the above terms

For ChinaWhys (Shanghai) Consulting Co Ltd

摄连咨询(上海)有限公司

Signed:



Date: 26 April 2013

Name: Mr. Peter Humphrey

### **Prevention of Corruption – Third Party Guidelines**

The GSK Anti-Bribery and Corruption Policy (POL-GSK-007) requires compliance with the highest ethical standards and all anti-corruption laws applicable in the countries in which GSK (whether through a third party or otherwise) conducts business. POL-GSK-007 requires all GSK employees and any third party acting for or on behalf of GSK to ensure that all dealings with third parties, both in the private and government sectors, are carried out in compliance with all relevant laws and regulations and with the standards of integrity required for all GSK business. GSK values integrity and transparency and has zero tolerance for corrupt activities of any kind, whether committed by GSK employees, officers, or third-parties acting for or on behalf of the GSK.

**Corrupt Payments** – GSK employees and any third party acting for or on behalf of GSK, shall not, directly or indirectly, promise, authorise, ratify or offer to make or make any “payments” of “anything of value” (as defined in the glossary section) to any individual (or at the request of any individual) including a “government official” (as defined in the glossary section) for the improper purpose of influencing or inducing or as a reward for any act, omission or decision to secure an improper advantage or to improperly assist the company in obtaining or retaining business.

**Government Officials** – Although GSK’s policy prohibits payments by GSK or third parties acting for or on its behalf to any individual, private or public, as a “quid pro quo” for business, due to the existence of specific anticorruption laws in the countries where we operate, this policy is particularly applicable to “payments” of “anything of value” (as defined in the glossary section), or at the request of, “government officials” (as defined in the glossary section).

**Facilitating Payments** – For the avoidance of doubt, facilitating payments (otherwise known as “greasing payments” and defined as payments to an individual to secure or expedite the performance of a routine government action by government officials) are no exception to the general rule and therefore prohibited.

### **GLOSSARY**

The terms defined herein should be construed broadly to give effect to the letter and spirit of the ABAC Policy. GSK is committed to the highest ethical standards of business

dealings and any acts that create the appearance of promising, offering, giving or authorising payments prohibited by this policy will not be tolerated.

Anything of Value: this term includes cash or cash equivalents, gifts, services, employment offers, loans, travel expenses, entertainment, political contributions, charitable donations, subsidies, per diem payments, sponsorships, honoraria or provision of any other asset, even if nominal in value.

Payments: this term refers to and includes any direct or indirect offers to pay, promises to pay, authorisations of or payments of anything of value.

Government Official shall mean:

- Any officer or employee of a government or any department, agency or instrument of a government;
- Any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government;
- Any officer or employee of a company or business owned in whole or part by a government;
- Any officer or employee of a public international organisation such as the World Bank or United Nations;
- Any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or
- Any candidate for political office



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**CLIENT CONFIDENTIAL**

**21 April 2013**

To: Dr. Mark Reilly, Chairman  
GlaxoSmithKline (China) Investment Co Ltd  
6<sup>th</sup> Floor, The Headquarters Building  
No. 168 Xizang Middle Road  
Shanghai 200001, China

**ChinaWhys (Shanghai) Consulting Co Ltd**  
摄连咨询(上海)有限公司  
上海南京西路 1168 号  
中信泰富广场 35-107 号  
邮编: 200041

Dear Mr. Reilly,

**Proposed Investigation – Project Scorpion**

Further to the recent contacts between yourself and ChinaWhys Co Ltd (“ChinaWhys”), I have pleasure in submitting the following proposal for your consideration.

**About ChinaWhys**

ChinaWhys is an independent China-focused risk management practice providing discreet risk mitigation solutions, investigation, consulting and research services to corporate clients in matters of high sensitivity throughout Greater China and Asia. We operate through an extensive and discreet network of associates across China and elsewhere in the region.

We have conducted such services in China on behalf of large, medium and small western multinationals in numerous industries, as well as non-governmental organizations, chambers of commerce, and high wealth individuals.

**Project Name**

This prospective engagement has been codenamed “Project Scorpion”.

**Background**

Our understanding of this matter is based on a limited briefing and any error is regretted. We understand that GSK, listed on the London and New York bourses, is one of the leading global health companies involved in research and development of a broad range of innovative medicines and brands. Headquartered in the UK, GSK has offices in more than 115 countries and an extensive manufacturing network around 70 sites globally. In China GSK operates one R&D centre and six manufacturing sites making products in prescription medicines and vaccines. In

addition it also provides products to the China market covering a wide range of therapeutic drugs as well as consumer healthcare products.

Ms. Vivian Shi Wen ("Vivian") was director of central government affairs of GSK China, based in Shanghai. In December 2012, given the findings on her irregular expense claim records, GSK China and Vivian by mutual agreement terminated Vivian's employment contract with the company.

Regardless of the expense claim irregularities, Vivian had been suspected for some time of being the behind-the-scenes author of a smear campaign against GSK stretching over a period of about 14 months and involving at least 23 anonymous letters sent to government agencies around the country and several emails sent to GSK's top management.

The letters alleged that bribery is rife in GSK China sales and that the practice was endorsed by senior management. In response to the allegations, GSK conducted internal investigations but could not substantiate the allegations. GSK believes Vivian orchestrated these attacks on the company but it says it has no direct evidence of this.

In March 2013 an email was sent to GSK's CEO Andrew Witty and five other senior executives in the US and the UK, alleging that GSK China used its travel agent to funnel kickbacks to customers or doctors. In addition, attached to the email was a video recording of GSK China's president Mark Reilly, apparently filmed in his apartment. Security experts believe a camera had been secretly positioned on top of a TV set in his bedroom.

The clip was edited professionally in an effort to disguise the location, but it was obvious to Mark Reilly that the video was shot in his room. It is assumed the camera was installed when Dr. Reilly was away, and it had been removed by the time the email and clip were sent out.

GSK presumes the aim of this incident was to damage Reilly's reputation irretrievably and to prompt GSK to fire him. GSK reported the incident to local Chinese police (PSB) and Reilly relocated to a more secure residence with a surveillance camera fitted over his apartment door.

His travel schedule is widely known at the company, and it is assumed that someone must have leaked his schedule to Vivian or her accomplices or to some author of the incident.

GSK is concerned that Vivian may have local PSB contacts who could have helped to plant the camera in Reilly's room. It is also possible that she hired private investigators to do it.

Vivian is said to be very close to officials of the State Food and Drug Administration (SFDA) in Shanghai, the government agency which regulates pharmaceutical companies.

She is said to be married, with one daughter, and her husband is said to work for a university.

Since her departure from GSK, she is said to have been seeking employment with multinational pharmaceutical or health product manufacturers – without success up to date.

Vivian is said to be strongly disliked by her former GSK colleagues. Most people who used to work with her left the company.

In order to improve its understanding of the matter and in the interest of defending its reputation, GSK wishes to conduct a discreet information search into Vivian, her activities, track record with previous employers, and her political influence, to assess the potential risks that her activities may pose to GSK, and to gather any available evidence that Vivian orchestrated the smear campaign against GSK and Dr. Reilly.

### **Objective**

The objective of Project Scorpion is to assist GSK to mitigate the risks associated with the smear campaign through discreet investigative actions addressing the focal issues listed above.

### **Proposed Course of Action**

Based on the facts presented to us by GSK, it is now proposed to proceed as follows.

#### **■ *Collection and review of client information***

Before we commence our investigation, GSK will provide us with all necessary start-up information required to facilitate well-focused and economical inquiries, including:

- Full identifiers of Vivian Shi, including her full names in Chinese and English, CVs, HR data forms, ID number, copy of ID card, copy of business card, all known addresses, all known phone numbers, all known email addresses, all known social media platforms that she belongs to, copy of employment contract, recent photo, details of any known family members (possibly to be found in the emergency contacts section of her HR file), etc, to the best knowledge of GSK, if there is any.
- Details of employees who have worked with Vivian and the org chart which specifies the positions of these employees, and their contact details.
- Copies of any allegation emails in GSK's possession. Any such emails should be provided in the form of detached eml files in their original format so that we can attempt a trace analysis on them.
- A copy of Vivian's profile from *Weibo*, mentioned by GSK in our briefing.
- Names of SFDA officials with whom Vivian is known to be close and any other government agencies that Vivian was routinely in contact with in the course of her work.
- Full address of Mark Reilly's former residence where the camera was installed. Details of landlord. Details of building management and security department there.
- Any additional anecdotal or 'hearsay' information about the activities of the suspects and related entities and associates.

■ **Phase 1 Investigation**

Once the information is received, we will thoroughly review the above start-up information and then initiate inquiries into Vivian and her contacts.

- Our analysts will conduct thorough desktop research in Chinese and English comprising searches of public and private online electronic resources, business databases, especially Chinese-language sources, on Vivian in order to gather all information about her that is available in open sources without alerting her, to build a profile and explore her social network, and to develop leads for our inquiries.
- We will aim to identify the security service firm which provides guard services to Reilly's former residence building and learn whether it has kept any CCTV security film from the period when the illicit video was shot (believed to be the first week of March 2013).
- We will conduct discreet inquiries with official agencies and knowledgeable contacts into Vivian and her family members in an effort to ascertain the strength of any political and governmental connections they may have.
- We will identify sources close to Vivian from her various past employments and discreetly approach them to gather further information about Vivian's connections with government and SFDA hierarchies, and to gather additional information about her personal behaviour, track record and past departures from employers.
- We will discreetly approach knowledgeable sources within the government and SFDA to obtain their view on the strength of any ties that Vivian could potentially use to harm GSK.
- We will also discreetly inquire into whether Vivian has close contacts with the Shanghai PSB, and whether it is possible that such PSB contacts could have helped to bug Reilly's apartment with the hidden camera.
- As far as is this is safely and technically possible, our contacts will be recorded.
- When conducting the above search and inquiry, we will use our best efforts to ensure that such actions will not alert Vivian or pose any harm to the GSK's decent relationship with government agencies.
- Upon completion of our inquiries we will provide a report containing our findings and any collected evidence.

**Potential Optional Follow-Up Phases**

While we always endeavor to complete such investigations as far as possible in a single round of inquiries, there are occasions when additional phases of inquiry or additional actions may be required in order close the loop on a complex matter. If required by GSK, such additional actions in this matter could potentially include some of the following:

- E-review of workplace PC and email data to search for additional leads and evidence.

- Orchestration of surveillance actions to identify activities and affiliations of the subject.
- Drill-down inquiries on particular parties and issues identified in the course of Phase 1.
- Related discreet inquiries in additional jurisdictions based on leads uncovered in Phase 1.
- Internal investigation comprising interviews with GSK personnel.

The scope and costs of any such additional actions would be negotiated and agreed with GSK separately from the Phase 1 outlined above, before any such additional actions are initiated.

#### **Caveat: Information Restrictions**

Please note that China has been undergoing a political leadership change this year and this is a period of political tension, with a tightening of control over information flow. We have seen sudden swings and arbitrary regulatory restrictions on the availability of certain documentary data in recent months such as company registration details and ownership, financials and other details, and personal data, in certain parts of the country. The nature, location, scope and timing of such regulatory restrictions when they occur are unpredictable. We would make our best efforts to complete the assignment by gathering all available information through legal means.

#### **Utilization of Findings**

Our findings are exclusively for the use of GSK and its legal advisers in assessing and mitigating business risk and not for publication or distribution to any other third party. Should GSK wish to use our findings in any legal proceedings, this could require additional work in collaboration with your legal counsel to package any legally admissible material for evidentiary purposes. The ChinaWhys name may not be revealed to third parties without our prior written consent, which will not be unreasonably withheld and which will be based upon our assessment of security risks posed to ChinaWhys and its personnel.

#### **Project Fees**

For Phase 1 of this investigation we will require a professional fee of RMB 220,000.

Our professional fees are quoted exclusive of PRC VAT, which will be applied to our invoices.

In addition to our professional fees, reasonable disbursements for travel, accommodation, registry and database charges, duty meals, etc, will be charged at cost. These out-of-pockets will not exceed the equivalent of 15% of our professional fees.

The fees for any subsequent phases or actions would be negotiated separately based on the scope of work anticipated.

#### **Conduct of the Assignment**

As information develops in the course of the project, new leads of inquiry may be identified in new jurisdictions or directions requiring additional work to be carried out. We will review such information with you to determine its relevance to the objectives and to assess whether any such new work should be conducted and further budget allocated. Any additional phase of the project would be defined and agreed in writing through these discussions.

**Reporting**

Upon completion of Phase 1, a report will be submitted to you. Before its submission any significant information that emerges during our inquiries will be communicated to you promptly. We estimate a completion period for Phase 1 of four working weeks. (The upcoming May Day public holiday in mainland China will interrupt our work for several days.)

**Non-Solicitation**

For a period of two years from the signing of this letter GSK shall not solicit, offer employment, hire, or offer assignments directly or indirectly to any employee or subcontractor or supplier of ChinaWhys, without the prior written consent of ChinaWhys. Also, GSK shall not attempt to entice, lure away or refer directly or indirectly any employee or subcontractor or supplier of ChinaWhys to any other third party.

**Terms of Business**

Other working conditions are as stated in the Consultancy Agreement between GSK and us (attached).

**Acceptance**

We much look forward to cooperating with you on this important project. Should the issues and terms set out in this proposal be acceptable, would you please sign and return a copy of this letter. We will be available to start work on receipt of payment of the invoice for the retainer fee.

Thank you for the opportunity to be of service to Client. If you would like to further clarify any of the matters raised in this document please contact me. We look forward to hearing from you at your convenience.

Yours sincerely,



Mr. Peter Humphrey  
Managing Director,  
ChinaWhys

Proposal has been accepted by:

Signature:

NAME:

Title:

## CHINADAILY USA

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# Foreigners nabbed for personal info trafficking

Updated: 2013-08-27 05:59

(Xinhua)

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SHANGHAI - Police in Shanghai have detained a foreign couple who were suspectedly involved in operating illegal research companies and trafficking personal information, police sources said on Monday.

Peter William Humphrey, a 57-year old British national, and Yu Ying Zeng, 60, who was an American and identified as Peter's wife, have been arrested by police on Aug 16, according to the police.

Investigation found that the couple illegally trafficked a huge amount of personal information on Chinese citizens to seek profits via registering so-called research companies in Hong Kong and Shanghai since 2003.

Among the 500 investigative reports seized by police, more than ten were found to have infringed on Chinese citizens' right of privacy, police said.

The personal information traded by the couple included residence addresses, family members, exit-entry information and real estate, according to police.

The couple have confessed to their criminal facts and apologized to the Chinese government, police said.

Police in Shanghai have arrested 126 people for illegal personal information trafficking and solved more than 140 related cases in the first 10 days of August.

8.03K

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# The Fraud Examiner

## HOW FRAUD INVESTIGATION JUST GOT HARDER IN CHINA

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### *Exploring the Impact of China's clampdown on public records*

May 2013

By Peter Humphrey, CFE

Over the past 15 years, I have witnessed the gradual emergence of an investigation industry in China. It began from crude anti-counterfeit outfits and family investigation agencies and gradually extended to the more sophisticated areas of due diligence, fraud investigation and forensics, as well as compliance and FCPA investigations. In the same period, we saw increasing availability of what in most countries we call "public records," including company registration files, annual returns and some limited, but useful, personal data.

The availability of such records combined with a CFE's skill set of forensic accountants enabled anti-fraud professionals to do their job in a country where foreign investors feel at risk due to a high white-collar crime rate, a lack of transparency and strong cultural barriers in business operations.

The promising environment that evolved for the fight against fraud and bribery in company operations in China has suffered a major setback due to a sudden government action to suppress certain data contained in such records. Why has this U-turn happened, and what is its impact on anti-fraud work?

In January 2013, forensic and investigation firms -- and local law firms -- found that they or their search agents could no longer freely access records filed with the Administration of Industry and Commerce (AIC) bureaus around the country. The AIC registers, incorporates, inspects and regulates all companies in China, and collects their annual returns. These records, until recently accessible in full, contain useful data and documents relating to the birth, evolution and status of a company, names and personal details of shareholders, annual financial data and annual audit reports.

It is by examining these records in conjunction with a forensic accounting review that a CFE here can close the circle on a fraud -- for example, by proving that Mr. X, an employee of Company Z, has set up his own firm (and, by the way, with no physical existence) and inserted this phantom into the sales chain as part of a large-scale distribution fraud against his employer.

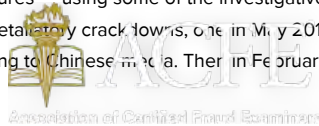
Or, it can enable a would-be investor considering buying shares in a Chinese company listed on Nasdaq to determine that the company has inflated its sales data and that its principals have actually been involved in a string of stock-listing frauds.

During 2011 and 2012, short-seller Muddy Waters not only shorted Chinese stocks (such as Sino Forest) that it had identified (possibly correctly) as fraudulent, it also published its findings on each firm in a manner viewed by authorities in Beijing as rabidly anti-Chinese, thus putting the Chinese Foreign Ministry on the back foot and unnecessarily provoking a government reaction. Soon after that, *Bloomberg* ran exposés on the business web and assets of a (now disgraced) Chinese Politburo member Mr. Bo Xi Lai and his wife, and then gave the family of China's new President-to-be Mr. Xi Jinping similar treatment. In a third such article, the *New York Times* threw oil on the fire in October with a detailed piece on the wealth of Premier Wen Jiabao's family.

Exhibit

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For a moment it appeared that these publishing adventures — using some of the investigative techniques of the forensic investigators, such as analysing AIC records — were making China's ruling elite wobble. In retaliation crack downs, one in May 2012 and one in January 2013, more than 1,000 local investigators and their alleged sources each time were detained, according to Chinese media. Then in February this year, the government issued strict new rules to restrict access to what it called "personal information."


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Critics describe this clampdown as an attempt to protect corrupt government officials from exposure. But as an anti-fraud worker in China serving purely corporate clients on corporate matters or in litigation support I find this a very dark day for due diligence and forensics work. I find this a step backwards that will make due diligence and catching fraudsters harder. We will have to be even more creative from now on.

As the recent disaster of a \$580 million fraud at a Chinese company acquired by Caterpillar shows, due diligence in China is a vital part of M&A for any sensible acquirer. If Caterpillar had done the kind of due diligence combining accounting with background investigation, retrieval of AIC records and discreet supporting inquiries, it might have spotted the fraud before doing the deal last year. But today, even if it wanted to take that approach, it would find it much harder to do as a result of the clampdown on public records.

Harbin Electric, a Chinese firm publicly-listed in the U.S. via reverse merger, i.e. a "backdoor listing," claimed in SEC filings that one of its largest clients in 2009 was a car seat maker to whom it sold motors, earning 10 percent of its revenue for the year, and that the A/R due from this client was \$10 million by that year's end. A discreet interview with a sales engineer working for the customer, however, revealed that the customer had bought just \$58,300 of goods between 2006 and 2007 and bought nothing else from Harbin Electric after that. This publicized case was an example of a widespread method of deception whereby Chinese firms exploited regulatory gaps and differences between Chinese company names and their English translations to file records and numbers in the U.S. that hugely differ from those they filed in China. For the U.S. audience such firms were faking revenue data in order to ramp up their share price in the U.S. market. Middlemen who took these companies abroad fabricated financial statements and got accounting firms to window-dress them, and supplied fake bank statements, fund transfer notes, bank drafts, delivery notes, etc. The brokers eager for these deals to be completed deliberately limited the due diligence scope as they would benefit from these listings going through regardless of any future losses to investors. In another example of this, we saw a rigged financial due diligence report done by "qualified accountants" engaged by a PE broker on a Chinese juice maker that was being groomed for listing in the U.S. It showed revenue packaged to come (ostensibly) from seven large customers, each contributing an uncannily similar 13 to 15 percent of the total, and A/R from three of them in identical figures. They had concocted the totals that they wanted to report, and simply divided it by seven.

At the same time that this skulduggery was going on in these cases, a financial institution which was trying to decide whether to invest in these firms engaged us to perform independent behind-the-scenes due diligence which included retrieval of records and returns filed by these companies locally in China, a review by forensic investigators, and a comparison with SEC filings. This way, they spotted the rat and avoided making potentially loss-making share investments. Following this year's clampdown on the release of financial data from AIC files, this is no longer possible.

With financial returns and personal identification data less available to help connect the dots, fraud investigation and due diligence in China must rely more on human source inquiries, both with related parties and with insiders (such as managers, sales agents, production staff, suppliers and so on) to ascertain that real business exists; and a forensic internal review, if circumstances allow it, in order to identify not only signs of irregularities but to drill down into their origins. The costs of this work will be well justified if they can prevent or detect large losses.

*Peter Humphrey is the founder and Managing Director of ChinaWhys, a forensics firm specialising in China matters. He is Founding President of the China chapters of the Association of Certified Fraud Examiners (ACFE). He is fluent in Chinese and has dealt with China and other Communist countries for 38 years. He can be contacted at [peter.humphrey@chinawhys.com](mailto:peter.humphrey@chinawhys.com)*

#### Contact the ACFE

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<http://www.acfe.com/fraud-examiner.aspx?id=4294978054>

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## JUSTICE NEWS

Department of Justice  
Office of Public Affairs

FOR IMMEDIATE RELEASE

Monday, July 2, 2012

### **GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data**

#### **Largest Health Care Fraud Settlement in U.S. History**

Global health care giant GlaxoSmithKline LLC (GSK) agreed to plead guilty and to pay \$3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices, the Justice Department announced today. The resolution is the largest health care fraud settlement in U.S. history and the largest payment ever by a drug company.

GSK agreed to plead guilty to a three-count criminal information, including two counts of introducing misbranded drugs, Paxil and Wellbutrin, into interstate commerce and one count of failing to report safety data about the drug Avandia to the Food and Drug Administration (FDA). Under the terms of the plea agreement, GSK will pay a total of \$1 billion, including a criminal fine of \$956,814,400 and forfeiture in the amount of \$43,185,600. The criminal plea agreement also includes certain non-monetary compliance commitments and certifications by GSK's U.S. president and board of directors. GSK's guilty plea and sentence is not final until accepted by the U.S. District Court.

GSK will also pay \$2 billion to resolve its civil liabilities with the federal government under the False Claims Act, as well as the states. The civil settlement resolves claims relating to Paxil, Wellbutrin and Avandia, as well as additional drugs, and also resolves pricing fraud allegations.

"Today's multi-billion dollar settlement is unprecedented in both size and scope. It underscores the Administration's firm commitment to protecting the American people and holding accountable those who commit health care fraud," said James M. Cole, Deputy Attorney General. "At every level, we are determined to stop practices that jeopardize patients' health, harm taxpayers, and violate the public trust – and this historic action is a clear warning to any company that chooses to break the law."

"Today's historic settlement is a major milestone in our efforts to stamp out health care fraud," said Bill Corr, Deputy Secretary of the Department of Health and Human Services (HHS). "For a long time, our health care system had been a target for cheaters who thought they could make an easy profit at the expense of public safety, taxpayers, and the millions of Americans who depend on programs like Medicare and Medicaid. But thanks to strong enforcement actions like those we have announced today, that equation is rapidly changing."

Exhibit

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This resolution marks the culmination of an extensive investigation by special agents from HHS-OIG, FDA and FBI, along with law enforcement partners across the federal government. Moving forward, GSK will be subject to stringent requirements under its corporate integrity agreement with HHS-OIG; this agreement is designed to increase accountability and transparency and prevent future fraud and abuse. Effective law enforcement partnerships and fraud prevention are hallmarks of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which fosters government collaboration to fight fraud.

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### Criminal Plea Agreement

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Under the provisions of the Food, Drug and Cosmetic Act, a company in its application to the FDA must specify each intended use of a drug. After the FDA approves the product as safe and effective for a specified use, a company's promotional activities must be limited to the intended uses that FDA approved. In fact, promotion by the manufacturer for other uses – known as “off-label uses” – renders the product “misbranded.”

Paxil: In the criminal information, the government alleges that, from April 1998 to August 2003, GSK unlawfully promoted Paxil for treating depression in patients under age 18, even though the FDA has never approved it for pediatric use. The United States alleges that, among other things, GSK participated in preparing, publishing and distributing a misleading medical journal article that misreported that a clinical trial of Paxil demonstrated efficacy in the treatment of depression in patients under age 18, when the study failed to demonstrate efficacy. At the same time, the United States alleges, GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18. The United States further alleges that GSK sponsored dinner programs, lunch programs, spa programs and similar activities to promote the use of Paxil in children and adolescents. GSK paid a speaker to talk to an audience of doctors and paid for the meal or spa treatment for the doctors who attended. Since 2004, Paxil, like other antidepressants, included on its label a “black box warning” stating that antidepressants may increase the risk of suicidal thinking and behavior in short-term studies in patients under age 18. GSK agreed to plead guilty to misbranding Paxil in that its labeling was false and misleading regarding the use of Paxil for patients under 18.

Wellbutrin: The United States also alleges that, from January 1999 to December 2003, GSK promoted Wellbutrin, approved at that time only for Major Depressive Disorder, for weight loss, the treatment of sexual dysfunction, substance addictions and Attention Deficit Hyperactivity Disorder, among other off-label uses. The United States contends that GSK paid millions of dollars to doctors to speak at and attend meetings, sometimes at lavish resorts, at which the off-label uses of Wellbutrin were routinely promoted and also used sales representatives, sham advisory boards, and supposedly independent Continuing Medical Education (CME) programs to promote Wellbutrin for these unapproved uses. GSK has agreed to plead guilty to misbranding Wellbutrin in that its labeling did not bear adequate directions for these off-label uses. For the Paxil and Wellbutrin misbranding offenses, GSK has agreed to pay a criminal fine and forfeiture of \$757,387,200.

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Avandia: The United States alleges that, between 2001 and 2007, GSK failed to include certain safety data about Avandia, a diabetes drug, in reports to the FDA that are meant to allow the FDA to determine if a drug continues to be safe for its approved indications and to spot drug safety trends. The missing information included data regarding certain post-marketing studies, as well as data regarding two studies undertaken in response to European regulators' concerns about the cardiovascular safety of Avandia. Since 2007, the FDA has added two black box warnings to the Avandia label to alert physicians about the potential increased risk of (1) congestive heart failure, and (2) myocardial infarction (heart attack). GSK has agreed to plead guilty to failing to report data to the FDA and has agreed to pay a criminal fine in the amount of \$242,612,800 for its unlawful conduct concerning Avandia.

"This case demonstrates our continuing commitment to ensuring that the messages provided by drug manufacturers to physicians and patients are true and accurate and that decisions as to what drugs are prescribed to sick patients are based on best medical judgments, not false and misleading claims or improper financial inducements," said Carmen Ortiz, U.S. Attorney for the District of Massachusetts.

"Patients rely on their physicians to prescribe the drugs they need," said John Walsh, U.S. Attorney for Colorado. "The pharmaceutical industries' drive for profits can distort the information provided to physicians concerning drugs. This case will help to ensure that your physician will make prescribing decisions based on good science and not on misinformation, money or favors provided by the pharmaceutical industry."

### Civil Settlement Agreement

As part of this global resolution, GSK has agreed to resolve its civil liability for the following alleged conduct: (1) promoting the drugs Paxil, Wellbutrin, Advair, Lamictal and Zofran for off-label, non-covered uses and paying kickbacks to physicians to prescribe those drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex; (2) making false and misleading statements concerning the safety of Avandia; and (3) reporting false best prices and underpaying rebates owed under the Medicaid Drug Rebate Program.

**Off-Label Promotion and Kickbacks:** The civil settlement resolves claims set forth in a complaint filed by the United States alleging that, in addition to promoting the drugs Paxil and Wellbutrin for unapproved, non-covered uses, GSK also promoted its asthma drug, Advair, for first-line therapy for mild asthma patients even though it was not approved or medically appropriate under these circumstances. GSK also promoted Advair for chronic obstructive pulmonary disease with misleading claims as to the relevant treatment guidelines. The civil settlement also resolves allegations that GSK promoted Lamictal, an anti-epileptic medication, for off-label, non-covered psychiatric uses, neuropathic pain and pain management. It further resolves allegations that GSK promoted certain forms of Zofran, approved only for post-operative nausea, for the treatment of morning sickness in pregnant women. It also includes allegations that GSK paid kickbacks to health care professionals to induce them to promote and prescribe these drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex. The United States alleges that this conduct caused false claims to be submitted to federal health care programs.

GSK has agreed to pay \$1.043 billion relating to false claims arising from this alleged conduct. The federal share of this settlement is \$832 million and the state share is \$210 million.

This off-label civil settlement resolves four lawsuits pending in federal court in the District of Massachusetts under the qui tam, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the United States and share in any recovery.

**Avandia:** In its civil settlement agreement, the United States alleges that GSK promoted Avandia to physicians and other health care providers with false and misleading representations about Avandia's safety profile, causing false claims to be submitted to federal health care programs. Specifically, the United States alleges that GSK stated that Avandia had a positive cholesterol profile despite having no well-controlled studies to support that message. The United States also alleges that the company sponsored programs suggesting cardiovascular benefits from Avandia

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therapy despite warnings on the FDA-approved label regarding cardiovascular risks. GSK has agreed to pay \$657 million relating to false claims arising from misrepresentations about Avandia. The federal share of this settlement is \$508 million and the state share is \$149 million.

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Price Reporting: GSK is also resolving allegations that, between 1994 and 2003, GSK and its corporate predecessors reported false drug prices, which resulted in GSK's underpaying rebates owed under the Medicaid Drug Rebate Program. By law, GSK was required to report the lowest, or "best" price that it charged its customers and to pay quarterly rebates to the states based on those reported prices. When drugs are sold to purchasers in contingent arrangements known as "bundles," the discounts offered for the bundled drugs must be reallocated across all products in the bundle proportionate to the dollar value of the units sold. The United States alleges that GSK had bundled sales arrangements that included steep discounts known as "nominal" pricing and yet failed to take such contingent arrangements into account when calculating and reporting its best prices to the Department of Health and Human Services. Had it done so, the effective prices on certain drugs would have been different, and, in some instances, triggered a new, lower best price than what GSK reported. As a result, GSK underpaid rebates due to Medicaid and overcharged certain Public Health Service entities for its drugs, the United States contends. GSK has agreed to pay \$300 million to resolve these allegations, including \$160,972,069 to the federal government, \$118,792,931 to the states, and \$20,235,000 to certain Public Health Service entities who paid inflated prices for the drugs at issue.

Except to the extent that GSK has agreed to plead guilty to the three-count criminal information, the claims settled by these agreements are allegations only, and there has been no determination of liability.

"This landmark settlement demonstrates the Department's commitment to protecting the American public against illegal conduct and fraud by pharmaceutical companies," said Stuart F. Delery, Acting Assistant Attorney General for the Justice Department's Civil Division. "Doctors need truthful, fair, balanced information when deciding whether the benefits of a drug outweigh its safety risks. By the same token, the FDA needs all necessary safety-related information to identify safety trends and to determine whether a drug is safe and effective. Unlawful promotion of drugs for unapproved uses and failing to report adverse drug experiences to the FDA can tip the balance of those important decisions, and the Justice Department will not tolerate attempts by those who seek to corrupt our health care system in this way."

#### Non-monetary Provisions and Corporate Integrity Agreement

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In addition to the criminal and civil resolutions, GSK has executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). The plea agreement and CIA include novel provisions that require that GSK implement and/or maintain major changes to the way it does business, including changing the way its sales force is compensated to remove compensation based on sales goals for territories, one of the driving forces behind much of the conduct at issue in this matter. Under the CIA, GSK is required to change its executive compensation program to permit the company to recoup annual bonuses and long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. GSK may recoup monies from executives who are current employees and those who have left the company. Among other things, the CIA also requires GSK to implement and maintain transparency in its research practices and publication policies and to follow specified policies in its contracts with various health care payors.

"Our five-year integrity agreement with GlaxoSmithKline requires individual accountability of its board and executives," said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. "For

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example, company executives may have to forfeit annual bonuses if they or their subordinates engage in significant misconduct, and sales agents are now being paid based on quality of service rather than sales targets.”

“The FDA Office of Criminal Investigations will aggressively pursue pharmaceutical companies that choose to put profits before the public’s health,” said Deborah M. Autor, Esq., Deputy Commissioner for Global Regulatory Operations and Policy, U.S. Food and Drug Administration. “We will continue to work with the Justice Department and our law enforcement counterparts to target companies that disregard the protections of the drug approval process by promoting drugs for uses when they have not been proven to be safe and effective for those uses, and that fail to report required drug safety information to the FDA.”

“The record settlement obtained by the multi-agency investigative team shows not only the importance of working with our partners, but also the importance of the public providing their knowledge of suspect schemes to the government,” said Kevin Perkins, Acting Executive Assistant Director of the FBI’s Criminal, Cyber, Response and Services Branch. “Together, we will continue to bring to justice those engaged in illegal schemes that threaten the safety of prescription drugs and other critical elements of our nation’s healthcare system.”

“Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior,” said Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management. “Today’s settlement reminds the pharmaceutical industry that they must observe those standards and reflects the commitment of Federal law enforcement organizations to pursue improper and illegal conduct that places health care consumers at risk.”

“Today’s announcement illustrates the efforts of VA OIG and its law enforcement partners in ensuring the integrity of the medical care provided our nation’s veterans by the Department of Veterans Affairs,” said George J. Opfer, Inspector General of the Department of Veterans Affairs. “The monetary recoveries realized by VA in this settlement will directly benefit VA healthcare programs that provide for veterans’ continued care.”

“This settlement sends a clear message that taking advantage of federal health care programs has substantial consequences for those who try,” said Rafael A. Medina, Special Agent in Charge of the Northeast Area Office of Inspector General for the U.S. Postal Service. “The U.S. Postal Service pays more than one billion dollars a year in workers’ compensation benefits and our office is committed to pursuing those individuals or entities whose fraudulent acts continue to unfairly add to that cost.”

#### A Multilateral Effort

The criminal case is being prosecuted by the U.S. Attorney’s Office for the District of Massachusetts and the Civil Division’s Consumer Protection Branch. The civil settlement was reached by the U.S. Attorney’s Office for the District of Massachusetts, the U.S. Attorney’s Office for the District of Colorado and the Civil Division’s Commercial Litigation Branch. Assistance was provided by the HHS Office of Counsel to the Inspector General, Office of the General Counsel-CMS Division and FDA’s Office of Chief Counsel as well as the National Association of Medicaid Fraud Control Units.

This matter was investigated by agents from the HHS-OIG; the FDA's Office of Criminal Investigations; the Defense Criminal Investigative Service of the Department of Defense; the Office of the Inspector General for the Office of Personnel Management; the Department of Veterans Affairs; the Department of Labor; TRICARE Program Integrity; the Office of Inspector General for the U.S. Postal Service and the FBI.

This resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by Attorney General Eric Holder and Kathleen Sebelius, Secretary of HHS. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. Over the last three years, the department has recovered a total of more than \$10.2 billion in settlements, judgments, fines, restitution, and forfeiture in health care fraud matters pursued under the False Claims Act and the Food, Drug and Cosmetic Act.

Court documents related to today's settlement can be viewed online at [www.justice.gov/opa/gsk-docs.html](http://www.justice.gov/opa/gsk-docs.html).

Related Materials:

[Remarks by the Deputy Attorney General James M. Cole at the GSK Press Conference](#)

[Remarks by Acting Assistant Attorney General for the Civil Division Stuart F. Delery at the GSK Press Conference](#)

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12-842

Civil Division

Topic:  
Consumer Protection

Updated May 22, 2015

**CORPORATE INTEGRITY AGREEMENT**  
**BETWEEN THE**  
**OFFICE OF INSPECTOR GENERAL**  
**OF THE**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**AND**  
**GLAXOSMITHKLINE LLC**

**I. PREAMBLE**

GlaxoSmithKline LLC (GSK) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements).

Contemporaneously with this CIA, GSK is entering into Settlement Agreements with the United States. GSK will also enter into settlement agreements with various States (State Settlement Agreements) and GSK's agreement to this CIA is a condition precedent to those agreements. Effective October 26, 2010, GSK entered into a Settlement Agreement with the United States to resolve allegations regarding certain drugs manufactured at SB Pharmco's Cidra, Puerto Rico facility.

Prior to the Effective Date of this CIA (as defined below), GSK and GSK Affiliates (as defined below in Section II.C.10) established a worldwide voluntary compliance program designed to address the companies' operations globally. In the United States, the compliance program is designed to address, among other things, compliance with Federal health care program and FDA requirements (Compliance Program).

GSK shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. GSK may modify its Compliance Program as appropriate, but, at a minimum, GSK shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

GlaxoSmithKline LLC  
Corporate Integrity Agreement

## **II. TERM AND SCOPE OF THE CIA**

A. Unless otherwise specified, the period of the compliance obligations assumed by GSK and its Affiliates under this CIA shall be five reporting periods, as defined below. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. The first Reporting Period shall be from the Effective Date through December 31, 2013. The second and subsequent Reporting Periods shall be from January 1 through December 31 of each of the subsequent four calendar years.

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) GSK’s final Annual Report; or (2) any additional materials submitted by GSK pursuant to OIG’s request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. “Covered Persons” includes:

a. all owners of GlaxoSmithKline PLC who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading or in connection with the operation of employee long term incentive plans) and all directors of GlaxoSmithKline PLC;

b. all employees of GSK or any GSK Affiliate who are engaged in or supervise personnel who are engaged in any of the Covered Functions (as defined below in Section II.C.7); and

c. contractors, subcontractors, agents and other persons (including, but not limited to, third party vendors who provide services relating to the Covered Functions) who perform any of the Covered Functions on behalf of GSK or any GSK Affiliate and who in that capacity either: (i) interact directly with health care professionals (HCPs), healthcare institutions (HCIs), or consumers; or (ii) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term Covered Persons does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “Relevant Covered Persons” includes all Covered Persons who engage in Covered Functions or who supervise Covered Persons who engage in Covered Functions.
3. “Government Reimbursed Products” refers to all GSK prescription<sup>1</sup> pharmaceutical products that are marketed or sold by GSK (including by its Pharma, Stiefel, Vaccines, and Oncology division) in the United States (or pursuant to contracts with the United States) that are reimbursed by Federal health care programs.
4. The term “Promotional Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to any applicable review committees, including GSK’s Copy Approval Team (CAT).
5. The term “Product Related Functions” includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to HCPs and HCIs about Government Reimbursed Products, including those functions relating to GSK’s CAT or other applicable review committee(s) and activities by GSK’s North America Medical Affairs department (Medical Affairs); (b) contracting with HCPs and HCIs in the United States to conduct post-marketing clinical trials, investigator sponsored studies (ISSs), and other post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and

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<sup>1</sup> GSK represents that its Consumer Healthcare business unit shall not market, detail, or otherwise promote prescription pharmaceutical products for the duration of the CIA. Should the Consumer Healthcare business unit begin to do so, it shall become subject to the terms of the CIA.

disclosure of articles or study results relating to post-marketing clinical trials and other post-marketing studies for Government Reimbursed Products (including studies of investigational and other uses and indications outside the currently approved uses and conditions of use); and (d) activities related to the submission of information about Government Reimbursed Products to compendia (such as DrugDex or other compendia of information about Government Reimbursed Products as defined below in Section III.B.3.t.)

6. The term “Payer Related Functions” refers to activities of GSK’s Policy, Payers and Vaccines (PPV) Unit and includes Promotional Functions and Product Related Functions as they relate to interactions between GSK and entities that provide a drug health benefit program for Government Reimbursed Products, including but not limited to government payers (e.g., Medicaid and Medicare) or individuals or entities under contract with or acting on behalf of government payers and commercial health plans (collectively referred to as “Payers”). Payer Related Functions also includes interactions with Payers related to formulary placement, supplemental rebate agreements, and other types of rebate agreements.
7. The term “Covered Functions” refers to “Promotional Functions,” “Product Related Functions,” and “Payer Related Functions” collectively.
8. The term “Third Party Educational Activity” shall mean any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by GSK, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.
9. The term “Third Party Personnel” shall mean employees of entities with whom GSK currently has, or in the future does, enter into agreements to promote or co-promote a Government Reimbursed Product or to engage in joint promotional activities relating to such a product. GSK represents that: (1) the Third Party Personnel are employed by independent entities other than GSK; (2) GSK does not control Third Party Personnel; and (3) it would be commercially impracticable to

compel the compliance of Third Party Personnel with the requirements set forth in this CIA. GSK agrees to promote compliance by Third Party Personnel with Federal health care program requirements and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.8, and V.B.4 related to Third Party Personnel. Provided that GSK complies with the requirements of Sections III.B.2, V.A.8, and V.B.4, GSK shall not be required to fulfill the remaining CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

10. The term “GSK Affiliate” shall mean GlaxoSmithKline PLC and any other entity (other than GlaxoSmithKline LLC) that is majority owned or controlled, directly or indirectly, by GlaxoSmithKline PLC and whose employees or contractors perform Covered Functions.

D. Appendix D to the CIA sets forth the obligations to which GSK and its Affiliates agree relating to manufacturing operations in connection with the settlement regarding the Cidra facility reference above in the Preamble. To the extent that certain general provisions and obligations are not specifically addressed in Appendix D, the terms of this CIA shall apply to CGMP Activities, Manufacturing Covered Persons, and to GSK and its Affiliates as specified herein.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

GSK shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Compliance Responsibilities of Certain GSK Employees and the Board of Directors.**

1. *Compliance Officer.* Prior to the Effective Date, GSK appointed an individual to serve as Vice President and Compliance Officer for its North America Pharma division (Compliance Officer). GSK shall maintain a Compliance Officer for the term of the CIA. During the term of this CIA, the Compliance Officer shall be authorized to oversee compliance with Federal health care program and FDA requirements and with the requirements of this CIA. The Compliance Officer is, and shall continue to be, responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health

care program and FDA requirements. The Compliance Officer shall be a member of senior management of GSK, and shall report directly to the Senior Vice President for Governance, Ethics, and Assurance of GlaxoSmithKline PLC who, in turn, reports to the Chief Executive Officer of GlaxoSmithKline PLC. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of GlaxoSmithKline PLC or any authorized committee thereof (hereinafter, “the Board”), and shall be authorized to report on such matters to the Board at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by GSK as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer’s ability to perform the duties outlined in this CIA.

GSK shall report to OIG, in writing, any change in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer’s ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, GSK formed compliance committee known as the NA Pharma Risk Management & Compliance Board (hereafter “Compliance Committee”) which, in conjunction with the Compliance Officer, assists in the implementation and enhancement of the Compliance Program. GSK shall continue the Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as such as legal, Medical Affairs, regulatory affairs, sales, marketing, human resources, research and development, global manufacturing quality control, and operations.) In addition, GSK’s Audit function provides regular reports to the Compliance Committee. The Compliance Officer and the President of GSK shall co-chair the Compliance Committee. The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the GSK’s risk areas and shall oversee monitoring of internal and external compliance-related audits and investigations). The Compliance Committee shall meet at least quarterly.

GSK shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance

Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* The Board shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board shall, at a minimum, be responsible for the following:

a. The Board shall meet at least quarterly to review and oversee GSK's Compliance Program, including but not limited to the performance of the Compliance Officer and other compliance personnel. The Board shall evaluate the effectiveness of the Compliance Program, including, at a minimum, by receiving updates about the activities of the Compliance Officer and other compliance personnel and updates about adoption and implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with applicable Federal health care program and FDA requirements.

b. For each Reporting Period of the CIA, the Board shall adopt a resolution, signed by each individual member of the Board, summarizing its review and oversight of GSK's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board of Directors has made a reasonable inquiry into the operations of GSK's Compliance Program as applicable to the CIA (including its Appendices) for the time period **[insert time period]**, including the performance of the Compliance Officer and the compliance personnel who are Covered Persons under this CIA. The Board has concluded that, to the best of its knowledge, GSK has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at GSK.

GSK shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Deputy Compliance Officers.* Prior to the Effective Date, GSK appointed Deputy Compliance Officers (DCOs) for each U.S. Pharma commercial business unit and for NA Pharma Medical Affairs, and GSK shall maintain the DCOs for the term of the CIA. Each DCO shall be a member of senior management of his/her respective business unit(s) and shall report directly to the Compliance Officer. The DCOs shall be responsible for working together with the Compliance Officer to oversee the development and implementation of policies, procedures, and practices designed to ensure business unit compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. Any noncompliance job responsibilities of the DCOs shall be limited and shall not interfere with each DCO's ability to perform the duties outline in this CIA.

5. *Integrity Champions.* Prior to the Effective Date, GSK implemented a program through which indentified individuals serve as Integrity Champions within each U.S. Pharma commercial business unit. Each individual selected to be an Integrity Champion shall be at least a manager within his/her respective business unit, and the responsibilities undertaken as an Integrity Champion shall be in addition to the individuals' existing management responsibilities. Integrity Champions shall be responsible for facilitating local implementation of, and adherence to, GSK policies and procedures, Federal health care program and FDA requirements, and the requirements of this CIA. Integrity Champions shall meet with their respective DCO on a regular basis. The performance of Integrity Champions, as such, will be a factor in their annual performance reviews.

6. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain GSK officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: President, GSK; the heads of the U.S. Pharma commercial business units; Chairman, Research and Development; Vice President, Strategic, Planning and Operations; Senior Vice President, NA Medical Affairs; President, Pharmaceuticals Research and Development; President, Vaccines; and Vice

President, Stiefel North America Dermatology, and, to the extent that a business unit performs Covered Functions and is not covered by the certification of one of the above-listed individuals, such other executives, vice-presidents, and directors of business units as would be necessary to ensure that there is a Certifying Employee from each such business unit.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the \_\_\_\_\_ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and GSK policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the \_\_\_\_\_ [insert name of department or functional area] of GSK is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a conclusion in the certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

#### B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, GSK developed and implemented a written Code of Conduct. Within 120 days after the Effective Date, GSK shall distribute the written Code of Conduct to all Covered Persons. GSK shall make adherence to the Code of Conduct an element in evaluating the performance of all employees who are Covered Persons. The Code of Conduct includes, or within 120 days after the Effective Date shall be revised to address the following:

- a. GSK’s commitment to full compliance with all Federal health care program requirements and FDA requirements, including its

commitment to comply with all requirements relating to the Covered Functions;

b. GSK's requirement that all of its Covered Persons shall be expected to comply with all applicable Federal health care program requirements, FDA Requirements, and with GSK's own Policies and Procedures;

c. GSK's requirement that all Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by GSK, suspected violations of any Federal health care program requirements, FDA requirements, or of GSK's own Policies and Procedures;

d. the personal obligations of each Covered Person to comply with Federal health care program requirements, FDA requirements, and GSK's Policies and Procedures; and

e. the right of all individuals to use the Disclosure Program described in Section III.F, and GSK's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 120 days after the Effective Date, each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

GSK shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Third Party Personnel.* Within 120 days after the Effective Date and annually thereafter by the anniversary of the Effective Date, GSK shall send a letter to each entity employing Third Party Personnel. The letter shall describe GSK's obligations under the CIA and its commitment to full compliance with all Federal health care program requirements and FDA requirements. The letter shall include a description of GSK's Compliance Program. GSK shall attach a copy of its Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of GSK's Code of Conduct and a description of GSK's Compliance Program available to its employees who meet the definition of Third Party Personnel as set forth in Section II.C.9; or (b) represent to GSK that it has and enforces a substantially comparable set of code of conduct and Compliance Program for its employees who meet the definition of Third Party Personnel as set forth in Section II.C.9.

3. *Policies and Procedures.* To the extent not already accomplished, GSK shall implement written policies and procedures regarding the operation of the Compliance Program and GSK's compliance with Federal health care program and FDA requirements (Policies and Procedures). At a minimum, the Policies and Procedures must address the following:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in compliance with all applicable FDA requirements;
- c. appropriate ways to conduct Product Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in compliance with all applicable FDA requirements;
- d. appropriate ways to conduct Payer Related Functions in compliance with all applicable Federal health care program

requirements, including but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)); the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); applicable FDA requirements; and applicable state laws. During the term of the CIA, the Policies and Procedures shall be consistent with GSK's US Commercial Practices Policy regarding "Administration of Contracts with Payers."

- e. the materials and information that may be distributed by GSK sales personnel about Government Reimbursed Products and the manner in which GSK sales personnel respond to requests for information about non-FDA approved (or "off-label") uses of Government Reimbursed Products. These Policies and Procedures shall require that sales personnel may not engage in off-label promotion (directly or indirectly) and must refer all requests for information about off-label uses of Government Reimbursed Products to Medical Affairs;
- f. the materials and information that may be distributed by GSK personnel from the PPV Unit and the manner in which PPV personnel respond to requests for information about off-label uses of Government Reimbursed Products. These Policies and Procedures shall require that all requests for information about off-label uses of Government Reimbursed Products be referred to Medical Affairs (i.e., Medical Information Scientists (MISs), Medical Science Liaisons (MSLs), and/or Health Outcome Liaisons (HOLs));
- g. the materials and information (including product information and product dossiers about Government Reimbursed Products) that may be distributed by Medical Affairs and the mechanisms through, and manner in which, Medical Affairs receives and responds to requests for information from an HCP or another individual or entity about off-label uses of GSK's Government Reimbursed Products; the form and content of information disseminated by GSK in response to such requests; and the internal review and approval process for the information disseminated. These Policies and Procedures shall require that

GSK sales personnel obtain a signature from the medical professional who verbally requested the written information confirming what information was requested and the request was unsolicited.

The Policies and Procedures shall include a requirement that Medical Affairs develop a database (“Inquiries Database”) to track all requests for information about Government Reimbursed Products to Medical Affairs. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about GSK’s products: (1) date of Inquiry; (2) form of Inquiry (e.g., fax, phone, etc.); (3) name of the requesting HCP, HCI, or other individual or entity; (4) nature and topic of request (including exact language of the Inquiry if made in writing); (5) an evaluation of whether the Inquiry relates to information about an off-label use for the product; (6) nature/form of the response from GSK (including a record of the materials provided to the HCP or HCI in response to the request); and (7) the name of the GSK representative who called on or interacted with the HCP, customer, or HCI, if known;

- h. the materials and information that may be distributed or made available by GSK through social media and/or through direct-to-consumer advertising. These policies and procedures shall be designed to ensure that GSK’s activities in this area and the information distributed or made available complies with all applicable Federal health care program and FDA requirements, and have been reviewed and approved by GSK before they are disseminated;
- i. the manner and circumstances under which medical personnel from Medical Affairs interact with or participate in meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to unsolicited requests about off-label indications of Government Reimbursed Products;

- j. the development, implementation, and review of target plans for sales personnel and other GSK personnel who promote and sell Government Reimbursed Products (Target Plans). For each Government Reimbursed Product, the Policies and Procedures shall require that GSK review Target Plans for the product and the bases upon, and circumstances under which HCPs and HCIs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the Target Plans. The Policies and Procedures shall also require that GSK modify the Target Plans as necessary to ensure that GSK is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The Target Plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;
- k. the development, implementation, and review of policies and procedures (including excluded specialties lists) for the distribution of samples of, or coupons or vouchers for, Government Reimbursed Products (collectively “Sample Distribution Policies and Procedures”). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples, coupons, or vouchers from GSK. GSK shall modify the Sample Distribution Policies and Procedures as necessary to ensure that GSK is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements;
- l. consultant or other fee-for-service arrangements entered into with HCPs or HCIs relating to Covered Functions (including, but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events

and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and shall include requirements about the content and circumstances of such arrangements and events. The Policies and Procedures shall require that compensation be based on fair market value, include caps on the total amount of payment that may be provided annually, and that HCPs who sit on formulary boards or develop clinical guidelines are required to disclose their relationship with GSK;

- m. programs to educate sales personnel, including but not limited to presentations by HCPs at sales meetings and experience-based learning activities, if any. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;
- n. sponsorship or funding of grants to healthcare-related organizations and donations to community partners in the United States (including support of any educational programs they conduct for non-HCP audiences). These Policies and Procedures shall be designed to ensure that GSK's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements. In addition, the Policies and Procedures continue to limit the situations in which GSK shall make grants and donations and shall state that GSK does not provide funding in order to influence the use of GSK products or services;
- o. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.8 above. These Policies and Procedures shall be designed to ensure that any GSK funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements. Prior to the

Effective Date of the CIA, GSK implemented policies restricting funding for Third Party Educational Activity to a limited number of specific types of entities (i.e., academic medical centers and their affiliated teaching and patient care institutions and professional medical associations that represent HCPs responsible for the delivery of patient care). These Policies and Procedures prohibit funding for independent medical education by commercial providers. During the term of the CIA, the Policies and Procedures shall continue to require that GSK provide funding for Third Party Educational Activity in accordance with its Policies and Procedures and practices outlined in this Section III.B.3.o and below in Section III.M.4.

The Policies and Procedures shall also require that: (1) GSK disclose its financial support of the Third Party Educational Activity and, to the extent feasible consistent with subsection III.B.3.o.4 below, any financial relationships with faculty, speakers, or organizers at such Activity; (2) as a condition of funding, the third party shall agree to disclose GSK's financial support of the Third Party Educational Activity and to require faculty, speakers, or organizers at such Activity to disclose any financial relationship with GSK; (3) the Third Party Educational Activity have an educational focus; (4) the content, organization, and operation of the Third Party Educational Activity (including the faculty, educational methods, materials, and venue) be independent of GSK's control; (5) GSK support only Third Party Educational Activity that is non-promotional in tone/nature; and (6) GSK's support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Third Party Educational Activity that is fair, balanced, accurate and not misleading;

- p. review of promotional materials and information intended to be disseminated outside GSK by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during GSK's review and approval process and are elevated when appropriate. The Policies and

Procedures shall be designed to ensure that such materials and information comply with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall require that: (1) applicable review committees (including the overall Copy Approval Team (CAT) and the CAT for each product) review all promotional materials prior to the distribution or use of such materials; (2) GSK's copy review and approval process ensure that FDA communications relevant to the product are considered and appropriately reflected in promotional materials and in a copy approval repository maintained by each CAT; and that (3) deviations from the standard review committee practices and protocols (including timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up;

- q. sponsorship, funding of, and disclosures relating to Product Related Functions. These Policies and Procedures shall be designed to ensure that GSK's funding, sponsorship, and disclosure complies with all applicable Federal health care program and FDA requirements;
- r. compensation (including through salaries, bonuses, or other means) for Covered Persons. These Policies and Procedures shall: (1) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of GSK's Government Reimbursed Products; and (2) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate off-label promotion of Government Reimbursed Products.

GSK represents that, prior to the Effective Date, it implemented a program in the United States to eliminate incentive compensative based on territory/individual level sales goals for prescriber-facing sales personnel (e.g., sales representatives) and their direct managers (Patient First Program). The Patient First Program is described in more detail below in Section III.H. GSK shall

continue its Patient First Program, or a substantially equivalent program, during the term of the CIA.

- s. GSK's right to recoup or cause the forfeiture of annual performance pay of GSK employees and Covered Executives if certain triggering events relating to misconduct by the employees or executives occur;
- t. the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter "Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (e.g., any changes based on GSK's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia.) The Policies and Procedures shall include a requirement that GSK conduct an annual review of all arrangements, processing fees, or other payments or financial support (if any) provided by GSK to any Compendia. GSK U.S. compliance personnel or other appropriately trained GSK personnel who are independent from the functional unit being reviewed shall be involved in this review;
- u. sponsorship by GSK of human subject research of Government Reimbursed Products (i.e., post-marketing clinical trials and post-marketing studies (collectively, "GSK-Sponsored Research")), and support by GSK of investigator-sponsored studies of Government Reimbursed Products (ISSs) (collectively, GSK-Sponsored Research and ISSs shall be referred to as "Research"), including the decision to provide financial or other support for Research; the manner in which Research support is provided; the publication of information about the Research, including the publication of information about the Research results and trial outcomes, and uses made of publications relating to Research;

Policies/Procedures regarding Sponsorship or Support of Studies Involving Government Reimbursed Products: GSK represents that it requires Research to be approved by its medical and/or research organizations. Under GSK's current policies and procedures, sales, marketing, or other commercial personnel may not participate in the design, conduct, or publication of GSK-Sponsored Research, with limited exceptions relating to non-interventional health outcomes studies (for which a relevant GSK medical group has oversight). GSK also represents that its human subject research and any resulting publications are intended to foster increased understanding of scientific, clinical or medical issues. To the extent not already accomplished, GSK shall require as a condition of its funding that all researchers disclose in any publication of Research, GSK's support and any financial interest the researcher may have in GSK.

Posting of Study Results and Protocols/Registry of Studies: GSK represents that, prior to the Effective Date, it developed a Clinical Study Register on which it posts, within a specified number of months from study completion and with rare exception, summary results from all GSK-Sponsored interventional Research studies of Government Reimbursed Products; and from GSK-Sponsored observational studies designed to inform the safety, efficacy or effectiveness, including cost-effectiveness, of Government Reimbursed Products; and from GSK-Sponsored meta-analyses and pooled analyses designed to inform appropriate, effective or safe use of Government Reimbursed Products. In addition, GSK posts summaries of its protocols for the studies and analyses described in the preceding sentence (including amendments that change the content of the summary) in its Register. GSK shall continue these practices throughout the term of the CIA.

In addition, GSK represents that it has established policies, systems, and practices to publish results from and information about discontinued studies on its Clinical Register, including the fact that the study terminated early. GSK shall continue these practices throughout the term of the CIA.

GSK represents that it registers summary results from all applicable GSK-sponsored clinical trials of GSK products and reports results of such clinical trials on the National Institutes of Health (NIH) sponsored website ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) in compliance with all Federal requirements. GSK shall continue to comply with Federal requirements or other applicable requirements relating to the registration and results reporting of clinical studies throughout the term of this CIA. In addition, if there is a change in Federal requirements or other applicable requirements relating to registration and results reporting of clinical study information, GSK shall fully comply with such requirements.

Publication of Study Results: GSK represents that it generally seeks publication of the results of all GSK-Sponsored interventional Research in peer-reviewed, searchable journals and imposes specified timeframes for the drafting and submission of manuscripts following completion of a study. For purposes of these publication requirements, GSK's publication policy includes certain GSK-Sponsored observational Research studies and certain GSK-Sponsored meta-analyses and pooled analyses.

In addition, GSK represents that it has established policies and "operating practices" governing scientific engagement, which included detailed directions regarding publications. Among other things, the operating practices require the implementation of data dissemination plans that establish prospective publication strategies for GSK-Sponsored Research and address requirements for appropriateness, accuracy, and balance in publications of GSK-Sponsored Research. In all publications about GSK-Sponsored Research, GSK shall acknowledge its role as the funding source.

In addition, GSK represents that it has established policies, systems, and practices designed to ensure that adverse event data is properly reported to the FDA. In addition, GSK requires investigators to report study-related information and data,

including data about adverse events before receiving final payment from GSK.

The standards, policies, and practices described above shall hereafter be referred to collectively as the “Research and Publication Practices.” GSK shall maintain its Research and Publication Practices (or standards and practices substantially equivalent to those set forth above) for studies initiated or completed after the Effective Date for the term of the CIA. To the extent that GSK intends to materially change these Research and Publication Practices, it shall notify the OIG about the change 30 days in advance of the effective date of the change;

- v. authorship of journal articles or other publications about GSK-Sponsored Research or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all financial relationships between the author and GSK, the identification of all authors or contributors (including professional writers) associated with a given publication, and that research results be made available to each author or contributor.

Authorship Requirements: GSK represents that it requires all authors of journal articles about GSK-Sponsored Research to adhere to International Committee of Medical Journal Editors (ICMJE) requirements regarding authorship except when a particular journal requires an alternative procedure. In addition, GSK requires all authors of articles on GSK-Sponsored Research to disclose any GSK financial support for the study and any financial relationship with GSK (including any financial interest the author may have in GSK or a GSK product). In addition, GSK represents that individuals may be considered an “author” on a GSK publication of GSK-Sponsored Research only if the individual has made substantial contributions to the study and has given final approval to the version of the publication ultimately published.

GSK shall require that its employees and medical writing contractors complete certain certification as to any GSK publication of GSK-Sponsored Research on which the individual is listed as an author or contributor. The standards, policies and practices described above shall be referred to collectively as “Authorship-Related Practices”; and

- w. disciplinary policies and procedures for violations of GSK’s Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 150 days after the Effective Date, the Policies and Procedures shall be made available to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), GSK shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education.

1. *General Training.* To the extent not already accomplished, within 120 days after the Effective Date, GSK shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain GSK’s:

- a. CIA requirements; and
- b. GSK’s Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* GSK shall provide annual training to each Relevant Covered Person relating to his or her specific job responsibilities. This training shall be known as Specific Training.

By December 31, 2012, each Relevant Covered Person engaged in Promotional Functions, Product Related Functions, or Payer Related Functions shall receive at least three hours of Specific Training in addition to the General Training required above.

For Relevant Covered Persons engaged in Promotional Functions or Product Related Functions, this Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Promotional Functions and to Product Related Functions;
- b. all applicable FDA requirements relating to Promotional Functions and to Product Related Functions;
- c. all GSK Policies and Procedures and other requirements applicable to Promotional Functions and Product Related Functions;
- d. the personal obligation of each individual involved in Promotional Functions and Product Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- f. examples of proper and improper practices related to Promotional Functions and Product Related Functions.

For Relevant Covered Persons engaged in Payer Related Functions, this Specific Training shall include a discussion of topics a-f above, as well as:

- g. all applicable Federal health care program requirements and FDA requirements relating to Payer Related Functions;

- h. GSK's systems and processes applicable to Payer Related Functions;
- i. all GSK Policies and Procedures and other requirements applicable to Promotional Functions and Product Related Functions;
- j. the personal obligation of each individual involved in Payer Related Functions to ensure that all information provided or reported to Payers is complete, accurate and not misleading;
- k. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- l. examples of proper and improper practices relating to Payer Related Functions.

New Relevant Covered Persons shall receive their Specific Training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or by December 31, 2012, whichever is later. A GSK employee who has completed the Specific Training shall oversee a new Relevant Covered Person's work, to the extent that the work relates to any of the Covered Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least three hours of Specific Training in each subsequent Reporting Period.

3. *Compliance Training for Management.* By December 31, 2012, GSK shall provide to managers of employees performing Covered Functions and supervisors of sales personnel (collectively "Management") at least three hours of specialized compliance-related training applicable to the functional area of the manager (Management Compliance Training). This training shall address the responsibility of Management to promote compliance and to identify and mitigate compliance-related risks in their functional areas.

New members of Management shall receive the Management Compliance Training within 30 days after becoming a member of Management or by December 31, 2012, whichever is later.

After receiving the initial Management Compliance Training described in this Section, each Relevant Covered Person shall receive at least three hours of Specialized Compliance Training in each subsequent Reporting Period.

4. *Board Member Training.* Within 150 days after the Effective Date, GSK shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a board member or within 120 days after the Effective Date, whichever is later.

5. *Certification.* Each Covered Person who is required to complete training shall certify, in writing or in electronic form, if applicable, that he or she has received such training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain these certifications, along with all course materials. These shall be made available to OIG, upon request.

6. *Qualifications of Trainer.* Persons responsible for providing the training described above shall be knowledgeable about the subject area of the training, including about applicable Federal health care program and FDA requirements.

7. *Update of Training.* GSK shall review its training annually, and, where appropriate, shall update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during internal audits or the IRO Reviews, the TRACER program (defined below in Section III.D), and any other relevant information.

8. *Computer-based Training.* GSK may provide the training required under this CIA through appropriate computer-based training approaches. If GSK chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training. All applicable requirements to provide a number

of “hours” of training as set forth in this Section III.C may be met with respect to computer-based training by providing the required number of “normative” hours as that term is used in the computer-based training industry.

D. Risk Assessment and Mitigation Process.

GSK represents that prior to the Effective Date, GSK began to implement a standardized process to allow GSK compliance, legal, and business unit leaders to assess and identify risks associated with Government Reimbursed Products that have field force support in the United States (GSK Products). This program is referred to as the Targeted Risk-based Analysis Compliance Evaluations and Review (TRACER) program and is described in more detail in Appendix C. TRACER involves an annual evaluation and mitigation of risks associated with the marketing of the GSK Products. GSK shall maintain a TRACER process for the duration of the CIA.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, GSK shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist GSK in assessing and evaluating its Covered Functions. More specifically, the IRO(s) shall conduct reviews that assess GSK’s systems, processes, policies, procedures, and practices relating to the Covered Functions (including Research and Publication Practices and Authorship-Related Practices) and the TRACER program (collectively “IRO Reviews”).

The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference. Each IRO engaged by GSK shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained including expertise in the pharmaceutical industry with regard to risk identification and mitigation in relation to pharmaceutical product marketing and promotion. Each IRO shall assess, along with GSK,

whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendices B and C, the IRO Reviews shall consist of three components: (1) Systems Reviews and Transactions Reviews relating to the Covered Functions; (2) Additional Items reviews; and (3) Systems Reviews and Transaction Reviews relating to the TRACER program. The Systems Reviews shall assess GSK's systems, processes, policies, and procedures relating to the Covered Functions and the TRACER program.

The IRO Reviews shall cover each of the six calendar years of the CIA. The first IRO Reporting Period shall cover the time from the Effective Date through December 31, 2012. The second through sixth IRO Reporting Periods shall cover, respectively, 2013 and each subsequent calendar year through 2017 (hereafter the "IRO Reporting Periods.") If there are no material changes in GSK's relevant systems, processes, policies, and procedures, the Systems Review shall be performed for the periods covering the second and fifth IRO Reporting Periods. If GSK materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform Systems Reviews for the IRO Reporting Periods in which such changes were made in addition to conducting the Systems Reviews for the second and fifth IRO Reporting Periods, as set forth more fully in Appendices B and C.

The IRO shall perform a limited Transactions Review for the first IRO Reporting Period as set forth more fully in Appendix B. For each of the remaining IRO Reporting Periods, the IRO shall perform full Transaction Reviews as set forth in Appendices B and C. The IRO(s) shall perform all components of each annual Transaction Review.

In addition, the Transactions Reviews for the second through sixth IRO Reporting Periods shall also include a review of up to three

additional areas or practices of GSK identified by the OIG in its discretion (hereafter “Additional Items”). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular IRO Reporting Period, the OIG will consult with GSK and may consider internal audit work conducted by GSK, the Government Reimbursed Product portfolio, the nature and scope of GSK’s promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Appendix B, GSK may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow GSK’s internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

The OIG shall notify GSK of the nature and scope of the IRO review for each of the Additional Items not later than 150 days prior to the end of each applicable IRO Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or GSK shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

*c. Retention of Records.* The IRO and GSK shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and GSK) related to the IRO Reviews.

*2. IRO Review Reports.* The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in each IRO Review Report is described in Appendices B and C.

*3. Validation Review.* In the event OIG has reason to believe that: (a) any of GSK’s IRO Reviews fails to conform to the requirements of this CIA; or (b) the IRO’s findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements

of the CIA and/or the findings or Review results are inaccurate (Validation Review). GSK shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of GSK's final Annual Report shall be initiated no later than one year after GSK's final submission (as described in Section II.B) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify GSK of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, GSK may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. GSK agrees to provide any additional information as may be requested by OIG under this Section III.E.3 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with GSK prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to GSK a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A.

#### F. Disclosure Program.

Prior to the GSK Effective Date, GSK and its Affiliates established a Disclosure Program that includes a mechanism (the toll free "Integrity Helpline") to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with GSK's or a GSK Affiliate's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement (including as they relate to CGMP Activities) believed by the individual to be a potential violation of criminal, civil, or administrative law. The Integrity Helpline may be used by employees of third party suppliers that contract with GSK. GSK and its Affiliates publicize, and shall continue to appropriately publicize, the existence of the Disclosure Program and the Integrity Helpline (e.g., via periodic e-mails to employees, by posting the information in prominent common areas, or through references in the Code of Conduct and during training.)

The Disclosure Program shall emphasize a nonretribution, non-retaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, GSK and/or any applicable Affiliate shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

GSK shall maintain, a disclosure log, which includes a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. This disclosure log shall be made available to OIG upon request.

#### G. Ineligible Persons.

##### 1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

2. *Screening Requirements.* GSK shall ensure that all prospective and current Covered Persons and Manufacturing Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. as part of the hiring or contracting process, GSK shall require all prospective and current Covered Persons and Manufacturing Covered Persons to disclose whether they are Ineligible Persons and shall screen potential Covered Persons and Manufacturing Covered Persons against the Exclusion Lists prior to engaging their services.
- b. GSK shall screen all Covered Persons and Manufacturing Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.
- c. GSK shall maintain a policy requiring all Covered Persons and Manufacturing Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section III.G affects GSK's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. GSK understands that items or services furnished by excluded persons are not payable by Federal health care programs and that GSK may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether GSK meets the requirements of Section III.G.

3. *Removal Requirement.* If GSK has actual notice that a Covered Person or Manufacturing Covered Person has become an Ineligible Person, GSK shall remove such Covered Person or Manufacturing Covered Person from responsibility for, or involvement with, GSK's business operations related to the Federal health care programs and shall remove such Covered Person or Manufacturing Covered Person from any position for which the Covered Person's or Manufacturing Covered Person's

compensation or the items or services furnished, ordered, or prescribed by the Covered Person or Manufacturing Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person or Manufacturing Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If GSK has actual notice that a Covered Person or Manufacturing Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's or Manufacturing Covered Person's employment or contract term, GSK shall take all appropriate actions to ensure that the responsibilities of that Covered Person or Manufacturing Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

#### H. Employee and Executive Incentive Compensation and Recoupment Policies and Practices.

Pursuant to its existing Patient First program, GSK agrees that it will not provide financial reward (through compensation, including incentive compensation or otherwise) or discipline (through tangible employment action) its prescribing-customer-facing field sales professionals (pharmaceutical sales representatives) or their direct managers based upon the volume of sales of GSK products within a given employee's own territory or the manager's district. The Patient First program includes evaluations for sales representatives based on business acumen, customer engagement, and scientific knowledge about GSK's products. GSK shall continue its Patient First Program, or a substantially equivalent program, during the term of this CIA. GSK commits to maintaining for at least the duration of the CIA, absent agreement otherwise with the OIG, the restrictions on such tangible employment decisions set forth in its Use of Territory/Individual Sales Data policy.

In addition, GSK shall establish and maintain throughout the term of this CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay (*i.e.*, annual bonus, plus long term incentives) for an executive who is discovered to have been involved in any significant misconduct (Executive Financial Recoupment Program). This financial recoupment program shall apply to both covered executives who are either current GSK employees or who are former GSK employees at the time of a Recoupment Determination. The

specific terms and conditions of the Executive Financial Recoupment Program are set forth in Appendix E. GSK commits to maintaining an Executive Financial Recoupment Program consistent with the terms of Appendix E for at least the duration of the CIA absent agreement otherwise by the OIG.

I. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, GSK shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to GSK conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that GSK or a GSK Affiliate has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. GSK shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

J. Reportable Events.

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any FDA requirements relating to the promotion of Government Reimbursed Products (including an FDA Warning Letter issued to GSK);
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by GSK.

A Reportable Event may be the result of an isolated event or a series of occurrences. A Reportable Event that meets the one of the definitions set forth above may arise from within the operations of GSK or any GSK Affiliate.

2. *Reporting of Reportable Events.* If GSK determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, GSK shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Sections III.J.1.a-c.* For Reportable Events under Sections III.J.1.a-c, the report to OIG shall include:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program or FDA authorities implicated;
- b. a description of GSK's actions taken to correct the Reportable Event; and
- c. any further that steps GSK plans to take to address the Reportable Event and prevent it from recurring.

GSK shall not be required to report any Reportable Event which is the subject of an ongoing investigation or legal proceeding by a governmental entity or its agents previously disclosed under Section III.I above.

4. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA authorities implicated.

K. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between GSK and the FDA that materially discusses GSK's or a Covered Person's actual or potential unlawful or improper promotion of GSK's products (including any improper dissemination of information about off-label indications), GSK shall provide a copy of the report, correspondence, or communication to the OIG. GSK shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and

shall provide the OIG with a description of the findings and/or results of the matter, if any.

L. Field Force Monitoring and Review Efforts.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: (1) a Speaker Monitoring Program; (2) direct field observations (Observations) of sales personnel; and (3) the monitoring and review of other records relating to sales personnel's interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.* With regard to speaker programs, GSK shall maintain processes to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements that the speaker may only use GSK approved materials and may not directly or indirectly promote the product for off-label uses.) GSK shall maintain a centralized electronic system through which all speaker programs are administered. This system shall establish controls regarding eligibility and qualifications of speakers and venues for the programs and require that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis conducted by GSK. GSK shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, GSK shall track and review the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs conducted during each Reporting Period. GSK shall require certified evaluations by sales personnel regarding whether a speaker program complied with GSK requirements, and in the event of non-compliance, GSK shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

To the extent not already accomplished, GSK shall institute a Speaker Monitoring Program under which GSK compliance or other appropriately trained GSK personnel who are independent from the functional area being monitored (hereinafter "GSK Monitoring Personnel") shall attend speaker programs during each Reporting Period and

conduct live audits of the programs (Speaker Program Audits). For the first Reporting Period, GSK shall conduct live audits of 150 speaker programs and for the subsequent Reporting Periods, GSK shall conduct live audits of 75 speaker programs. The programs subject to Speaker Program Audits shall be selected both on a risk-based targeting approach and on a sampling approach. For each program reviewed, personnel conducting the Speaker Program Audits shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and GSK representative activities during the program to assess whether the programs were conducted in a manner consistent with GSK's Policies and Procedures. GSK shall maintain the controls around speaker programs as described above, and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations.* As a component of the FFMP, GSK Monitoring Personnel shall conduct observations of field personnel (e.g., sales personnel, MSLs, HOLs, and account managers and directors from the PPV group) to assess whether the messages delivered and materials distributed to HCPs, HCIs, and others are consistent with applicable legal requirements and with GSK's Policies and Procedures. These observations shall be full day ride-alongs with the field personnel (Observations), and each Observation shall consist of directly observing all meetings between field personnel and HCPs during the workday. The Observations shall be scheduled throughout the year, selected by GSK Monitoring Personnel both on a risk-based targeting approach and on a sampling approach, include each therapeutic area and actively promoted product, and be conducted across the United States. At the completion of each Observation, GSK Monitoring Personnel shall prepare a report which includes:

- 1) the identity of the field personnel;
- 2) the identity of the GSK Monitoring Personnel;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with GSK policy; and
- 6) the identification of any potential off-label promotional activity or other improper conduct by the field personnel.

GSK Monitoring Personnel shall conduct at least 50 Observations during the first Reporting Period, and shall conduct at least 25 Observations during the subsequent Reporting Periods.

3. *Records Reviews.* As a component of the FFMP, GSK shall also review various types of records to assess sales personnel interactions with HCPs and HCIs in order to identify potential or actual compliance violations. For each Reporting Period, GSK shall develop and implement a plan for conducting Records Reviews associated with at least three Government Reimbursed Products and a sampling of the personnel supporting those products in regions across the country (as agreed with the OIG for each Reporting Period.) The OIG shall have the discretion to identify the three Government Reimbursed Products to be reviewed for each Reporting Period. The OIG will select the products based on information about GSK's products provided by GSK, upon request by the OIG no later than 60 days prior to the beginning of the Reporting Period, and other information known to the OIG. If the OIG does not identify the Government Reimbursed Products to be reviewed within the first 30 days of the Reporting Period, GSK shall select the three products to be reviewed.

These Records Reviews shall include the monitoring and review of: (1) records and systems relating to sales personnel interactions with HCPs and HCIs (including records from the electronic call reporting system used by sales personnel (which includes call notes), sales communications from managers, sample distribution records, and expense reports); (2) requests for medical information about, or inquiries relating to, Government Reimbursed Products; (3) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of sales personnel interactions with HCPs and HCIs; (4) sales personnel e-mails and other electronic records; and (5) recorded results of the Observations of sales representatives and applicable notes or information from the sales personnel managers.

4. *Reporting and Follow-up.* Personnel conducting the Speaker Program Audits, Observations, and Records Reviews shall have access to all relevant records and information necessary to assess potential or actual compliance violations. Results from the FFMP audits, including the identification of potential violations of policies and/or legal requirements, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate. In the event that a potential violation of GSK's Policies and Procedures or of legal or compliance requirements, including but not limited to potential off-label promotion, is identified during any aspect of the FFMP, GSK shall investigate the incident consistent with established policies and procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.J above, if applicable. Any compliance issues identified during a Speaker Program Audit,

Observation and/or Records Review and any corrective action shall be recorded in the files of the Compliance Officer (or compliance personnel designee).

GSK shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, GSK also shall provide the OIG with copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that GSK took as a result of such determinations. GSK shall make the Observation reports for all other Observations available to the OIG upon request.

M. Monitoring of Non-Promotional Activities.

To the extent not already accomplished, within 120 days after the Effective Date GSK shall develop and implement a monitoring program for the following types of activities: (1) consultant arrangement activities; (2) research-related activities; (3) publication activities; and (4) medical education grants. This program shall be referred to as the Non-Promotional Monitoring Program.

1. *Consultant Arrangement Activities.* To the extent that GSK engages U.S.-based HCPs or HCIs for services that relate to Promotional Functions or to Product Related Functions other than for speaker programs, research-related activities, or publication activities (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs or HCIs shall be referred to herein as Consultants. GSK shall require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by GSK.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a process to develop annual budgeting plans that identify the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the following year. The annual Consultant budgeting plans shall also identify the budgeted amounts to be spent on Consultant-related activities. GSK's Monitoring Personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate purposes in accordance with applicable GSK Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs or HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and type of work product to be generated.) Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by GSK Monitoring Personnel.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, GSK received the work product generated by the Consultant.

Within 120 days after the Effective Date, GSK shall establish a Consultant Monitoring Program through which it shall conduct audits for each Reporting Period (Consultant Program Audits) of at least 50 Consultant arrangements with HCPs for the first Reporting Period and 25 Consultant arrangements for subsequent Reporting Periods. The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a sampling approach. GSK Monitoring Personnel conducting the Consultant Program Audits shall review needs assessment documents, consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with GSK's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

2. *Research-Related Activities.* To the extent that GSK engages or supports U.S.-based HCPs or HCIs to conduct Research (as defined above in Section III.B.3.u), such HCPs and HCIs shall be referred to collectively as "Researchers". GSK shall require all Researchers to enter written agreements describing the scope of the clinical research or other work to be performed, the fees to be paid or support to be given, and compliance obligations for the Researchers. Researchers retained to conduct Research shall be paid

according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by GSK.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish an annual budgeting plan for Researchers that identifies the business or scientific need or scientific opportunity for, and the estimated numbers of, the various Researcher engagements and activities to occur during the year. The annual Researcher budgeting plan shall also identify the budgeted amounts to be spent on Researcher-related activities during the year. GSK Monitoring Personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Research arrangements and related events are used for legitimate purposes in accordance with GSK Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a process to ensure that a needs assessment has been completed to justify the retention of the Researcher prior to the retention of the Researcher. The needs assessment shall identify the business or scientific need for the information to be provided by the Researcher and provide specific details about the research arrangement (including, for example, information about the numbers and qualifications of the HCPs or HCIs to be engaged, a description of the proposed research to be done (including the research protocol) and type of work product to be generated). Any deviations from the Researcher budgeting plans shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by GSK Monitoring Personnel.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall amend its policies and procedures in a manner designed to ensure that each Researcher performed the work for which the Researcher was engaged.

Within 120 days after the Effective Date, GSK shall establish a Researcher Monitoring Program through which it shall conduct audits for each Reporting Period (Researcher Program Audits). GSK shall review 20 Researcher arrangements with HCPs or HCIs for the first Reporting Period and 10 Researcher Arrangements for subsequent Reporting Periods. The Researcher Monitoring Program shall review Researcher arrangements both on a risk-based targeting approach and on a sampling approach. GSK Monitoring Personnel conducting the Researcher Program Audits shall review needs assessment documents, proposal and/or protocol documents, approval documents, contracts, and payments in order to assess whether the programs and arrangements were

supported by GSK and performed by the Researchers in a manner consistent with GSK's Policies and Procedures. Results from the Researcher Program Audits, including identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

3. *Publication Activities.* GSK represents that it generally does not engage HCPs or HCIs exclusively to produce articles or other publications relating to GSK-Sponsored Research, and that generally HCPs or HCIs who perform this work do so as part of an engagement for Research Related Activities. To the extent that, in connection with Research Related Activities, U.S.-based HCPs or HCIs produce articles or other publications relating to GSK-Sponsored Research (collectively "Publication Activities") such HCPs or HCIs shall be referred to as Authors. GSK shall require all Authors to enter written agreements describing the terms of the arrangement between GSK and the Author and compliance obligations of the Authors. Authors shall be paid according to the centrally managed, pre-set rate structure that is established for Research Related Activities but will not be paid separately for authorship or other publication-specific activity (provided that GSK may reimburse travel expenses incurred to make public presentations of data from GSK-Sponsored Research Studies). If, in a departure from usual practice, GSK engages an HCP or HCI for a stand-alone project involving the production of an article or other publication relating to GSK-Sponsored Research (*e.g.*, a review article summarizing research in a field that includes GSK-Sponsored Research), GSK will require a written agreement with the same compliance obligations as it requires of Author generally and will pay for the work according to the centrally managed, pre-set rate structure as applied to Consultants generally.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a process to develop annual plans that identify the business needs for and the estimated numbers of various Publication Activities (Publications Plans). The annual Publications Plan shall also identify the budgeted amounts to be spent on Publication Activities. GSK's U.S. compliance personnel shall be involved in the review and approval of such annual Publications Plans, including any modification of an approved plan. The purpose of this review shall be to ensure that Publication Activities and related events are used for legitimate purposes in accordance with GSK Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a needs assessment process for Publication Activities. This process

shall ensure that a needs assessment has been completed prior to the retention of an Author for a Publication Activity. The needs assessment shall provide specific details about Publication Activities to be performed (including a description of the proposed work to be done, type of work product to be generated, and the purpose for the work.) Any deviations from the Publications Plan shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by GSK Monitoring Personnel.

Within 120 days after the Effective Date, GSK shall establish a Publication Monitoring Program through which it shall conduct audits for each Reporting Period of at least 50 Publication Activities for the first Reporting Period and 25 Publication Activities for subsequent Reporting Periods. The Publication Monitoring Program shall select publications for review both on a risk-based targeting approach and on a sampling approach. GSK Monitoring Personnel conducting the Publication Monitoring Program shall review needs assessment documents, proposal documents, approval documents, contracts, payments and materials relating to the Publication Activities (including work product resulting from the Activities), in order to assess whether the activities were conducted in a manner consistent with GSK's Policies and Procedures. Results from the Publication Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

4. *Medical Education Grant Activities.* GSK represents that it provides grants for medical education of HCPs on a limited basis and that it provides such grants only to educational providers (including academic medical centers, hospital or delivery systems, or professional medical associations that represent HCPs who deliver patient care) that satisfy pre-set criteria established by GSK. Potentially eligible educational providers are selected annually and invited to submit grant proposals for a future fiscal year. GSK represents that it does not provide funding to any commercial providers of medical education.

GSK's Medical Affairs organization reviews the grant proposals from the potential providers and makes recommendations for approval based on objective criteria, compliance policies and procedures, and budget availability. GSK represents that its commercial organization (including the sales and marketing departments) has no involvement in, or influence over, the review and approval of medical education grants. GSK shall continue the medical education grant process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at

least 60 days prior to the implementation of any new system subsequent to the Effective Date.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 10 medical education grants for the first Reporting Period and 5 medical education grants for subsequent Reporting Periods. The Grants Monitoring Program shall select grants for review both on a risk-based targeting approach and on a sampling approach. GSK Monitoring Personnel conducting the Grants Monitoring Program shall review proposal documents (including grant requests), approval documents, contracts, payments and materials relating to the grant office's review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with GSK's Policies and Procedures. Results from the Grant Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

*5. Follow Up Reviews and Reporting.* In the event that a potential violation of GSK's Policies and Procedures or of legal or compliance requirements, including but not limited to potential improper promotion, are identified during any aspect of the Non-Promotional Monitoring Program, GSK shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.J above, if applicable. Any compliance issues identified during any Non-Promotional Monitoring Program referenced above, and any corrective action, shall be recorded in the files of the U.S. Compliance Department.

GSK shall include a summary of the Non-Promotional Monitoring Program and the results of the Non-Promotional Monitoring Program as part of each Annual Report. As part of each Annual Report, GSK also shall provide the OIG with descriptions of any instances identified through the Non-Promotional Monitoring Program in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated GSK's requirements or Policies and Procedures, and a description of the action(s) that GSK took as a result of such determinations. GSK shall make the documents relating to the Non-Promotional Monitoring Program available to the OIG upon request.

N. Notices to Health Care Providers, Entities, Payers. Within 90 days after the Effective Date, GSK shall send, by first class mail, postage prepaid with delivery confirmation, a notice containing the language set forth below to all HCPs and HCIs that GSK currently details. This notice shall be dated and shall be signed by GSK's President. The body of the letter shall state the following:

As you may be aware, GSK recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with the promotion and use of some of its products. This letter provides you with additional information about the settlement, explains GSK's commitments going forward, and provides you with access to information about those commitments.

In general terms, the Government alleged that GSK unlawfully promoted Wellbutrin, Paxil, Advair, Lamictal, and Zofran for uses not approved by the Food & Drug Administration (FDA) and that GSK engaged in other improper conduct relating to several of its other drugs including Avandia. To resolve these matters, GSK pled guilty to three misdemeanor criminal violations of the Federal Food, Drug & Cosmetic Act and agreed to pay a criminal fine of \$1 billion. In addition, the Government alleged that GSK violated the False Claims Act and GSK entered into three civil settlements to resolve these allegations pursuant to which GSK agreed to pay \$ 2 billion to the Federal Government and State Medicaid programs. More information about this settlement may be found at the following: **[GSK shall include a link to the USAO, OCL, and GSK websites in the letter.]**

As part of the federal settlement, GSK also entered into a five-year corporate integrity agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. The CIA is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, GSK agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by GSK's representatives to GSK's Compliance Department or the FDA.

GSK is fully committed to meeting the terms of the CIA and to sales and

marketing practices that promote compliance. We have fundamentally changed our procedures for compliance, marketing and selling in the United States. For example, we now compensate our medical sales representatives based on the quality of service they deliver to customers, not on sales targets.

Please call GSK at **XXXX** or **visit us at [insert name of web link]** if you have questions about the settlement referenced above or to report any instances in which you believe that a GSK representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by a GSK representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about the products to **XXXXX**.

Within 90 days after the Effective Date, GSK shall send to all Payers with whom GSK currently has contracts or enters into contracts for formulary access or rebates (including all state Medicaid programs), by first class mail, postage prepaid with delivery confirmation, a notice containing the language set forth. This notice shall be dated and shall be signed by GSK's President. The body of the letter shall state the following:

As you may be aware, GSK recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with the promotion and of some of its products. This letter provides you with additional information about the settlement, explains GSK's commitments going forward, and provides you with access to information about those commitments.

In general terms, the Government alleged that GSK unlawfully promoted Wellbutrin, Paxil, Advair, Lamictal, and Zofran for uses not approved by the Food & Drug Administration (FDA) and that GSK engaged in other improper conduct relating to several of its other drugs including Avandia. To resolve these matters, GSK pled guilty to three misdemeanor criminal violations of the Federal Food, Drug & Cosmetic Act (FDCA) and agreed to pay a criminal fine of \$ 1 billion. In addition, the Government alleged that GSK violated the False Claims Act and GSK entered into three civil settlements to resolve these allegations pursuant to which GSK agreed to pay \$ 2 billion to the Federal Government and State Medicaid programs.

More information about this settlement may be found at the following:  
**[GSK shall include a link to the USAO, OCL, and GSK websites in the letter.]**

As part of the federal settlement, GSK also entered into a five-year corporate integrity agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. The CIA is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, GSK agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify payers about the settlement and inform them that they can report any questionable practices by GSK's representatives to GSK's Compliance Department or the FDA.

GSK is fully committed to meeting the terms of the CIA and to sales and marketing practices that promote compliance. We have fundamentally changed our procedures for compliance, marketing and selling in the United States. For example, we now compensate our medical sales representatives based on the quality of service they deliver to customers, not on sales targets.

In addition, GSK is committed to promoting its products in a manner consistent with the FDA approved label for the product. GSK will pay rebates under applicable agreements (Rebates) involving a prior authorization or formulary requirement (a "Restriction") in relation to the drugs at issue in this settlement, and will not reduce or alter its Rebates due to such a Restriction, provided that the Restriction: (1) does not limit any patient from receiving such drugs, including at the point of sale, for uses that are consistent with the FDA-approved label for each product; (2) is applied consistently across the therapeutic class; (3) is consistent with GSK's policies, procedures and financial guidelines; and, (4) does not require the use of another manufacturer's drug for a use that is not consistent with the FDA approved label for the other product. This paragraph shall not be interpreted to require GSK to contract or not to contract with any Payer. GSK shall administer its agreements with Payers in a manner consistent with the requirements of this paragraph, including agreeing to amend or modify applicable agreements to be consistent with this provision.

Please call GSK at **XXXX** or **visit us at [insert name of web link]** if you have questions about the settlement referenced above or to report any instances in which you believe that a GSK representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by a GSK representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about the products to **XXXXX**.

The Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notices. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The log of all calls and messages received in response to the notices shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, GSK shall provide to the OIG a summary of the calls and messages received.

**O. Reporting of Physician Payments.**

Prior to the Effective Date, GSK began a voluntary Physician Payment Transparency Program through which GSK posted on its corporate website quarterly reports of payments to physicians for speaking and consulting fees. GSK shall continue to post such reports until the Annual Reporting requirements of Section III.O.1 take effect.

**1. *Reporting of Payment Information.***

**Quarterly Reporting:** On or before March 1, 2013, GSK shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities who or which received Payments (as defined in Section III.O.2) directly or indirectly from GSK during the fourth quarter of 2012 and the aggregate value of such Payments. Thereafter, 60 days after the end of each calendar quarter, GSK shall post on its website a report of the cumulative value of the Payments provided to each physician and Related Entity during the preceding calendar quarter.

**Annual Reporting:** On or before March 1, 2013, and 60 days after the end of each subsequent calendar year, GSK shall post on its website a report of the cumulative value

of the Payments provided to all U.S.-based physicians and Related Entities directly or indirectly from GSK during the prior applicable calendar year. Each quarterly and annual report shall be easily accessible and readily searchable.

Each listing made pursuant to this Section III.O shall include a complete list of all individual physicians or Related Entities to whom or which GSK made Payments in the preceding quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or name of Related Entity. The Payment amounts in the lists shall be reported in the actual amount paid for all physicians or Related Entity on the listing. For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city and state that the physician has provided to GSK for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

## 2. *Definitions and Miscellaneous Provisions.*

(i) GSK shall continue to make each annual listing and the most recent quarterly listing of Payments available on its website during the term of the CIA. GSK shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual and/or quarterly listings of Payments. Nothing in this Section III.O affects the responsibility of GSK to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entity.

(ii) For purposes of Section III.O.1, "Payments" is defined to include all "payments or other transfers of value" as that term is defined in §1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder. The term Payments includes, by way of example, the types of payments or transfers of value enumerated in §1128G(a)(1)(A)(vi) of the Affordable Care Act. The term includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom GSK would otherwise report a Payment if made directly to the physician. The term Payments also includes any payments or transfers of value made, directly by GSK or by a vendor retained by GSK to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

(iii) For purposes of its annual and quarterly website postings as described above, and only with regard to payments made pursuant to product research or development agreements and clinical investigations as set forth in § 1128G(c)(E) of the Affordable Care Act, GSK may delay the inclusion of such payments on its website listings consistent with § 1128G(c)(E) of the Act and any subsequent regulations promulgated thereunder.

(iv) The term “Payments” does not include transfers of value or other items that are not included in or are excluded from the definition of “payment” as set forth in § 1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder.

(v) For purposes of this Section III.O, the term “Related Entity” is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

P. Other Transparency/Disclosure Initiatives.

GSK represents that it posts on its company website the following information with respect to both grants and charitable contributions in the United States: GSK shall continue to post (and provide updates to) the above-described information about grants and charitable contributions throughout the term of this CIA. GSK shall notify the OIG in writing at least 60 days prior to any change in the substance of its policies regarding the funding of grants and charitable contributions or posting of the above-referenced information relating to such funding.

GSK shall require all Consultants to comply fully with all applicable disclosure obligations relating to their relationship with GSK that may be externally imposed on the Consultants based on their affiliation with formulary or P&T committees or committees associated with the development of treatment protocols or standards. GSK shall maintain this requirement throughout the term of this CIA. GSK represents that within 120 days after the Effective Date, GSK shall, if necessary, amend its policies relating to Consultants to explicitly state that GSK requires all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with GSK that may be externally imposed on the Consultants based on their affiliation with formulary, P&T committees, or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any

amendment to its contracts with Consultants and in any new contracts with Consultants entered into after 150 days following the Effective Date, GSK shall include an explicit requirement that the Consultants fully comply with all applicable disclosure requirements, as referenced above in this paragraph. GSK shall continue these disclosure requirements throughout the term of this CIA.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall post or make available information on its company website about FDA postmarketing commitments (PMCs). The GSK website or links included therein shall provide access to general information about the PMC process, descriptions of ongoing GSK studies, and information about the nature and status of the post-marketing commitments. GSK shall continue to post or make available the above-described information about PMCs on its website or links included therein throughout the term of this CIA.

#### **IV. CHANGES TO BUSINESS UNITS OR LOCATIONS**

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, GSK changes locations or closes a business unit or location related to or engaged in any of the Covered Functions or in CGMP Activities, GSK shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, GSK purchases or establishes a new business unit or location related to or engaged in any of the Covered Functions or in cGMP Activities, GSK shall notify OIG no later than five days after the date that the purchase or establishment of the new business unit or location is publicly disclosed by GSK. This notification shall include the address of the new business unit or location, phone number, fax number, the location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which GSK currently submits claims (if applicable). Each new business unit or location and all Covered Persons or Manufacturing Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, GSK proposes to sell any or all of its business units or locations that are subject to this CIA (including the terms of Appendix D), GSK shall notify OIG of the proposed sale at no

later than five days after the sale is publicly disclosed by GSK. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

## **V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Implementation Report. Within 150 days after the Effective Date, GSK shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the members of the Board of Directors referenced in Section III.A.3;
4. the names of the DCOs required by Section III.A.4;
5. the names and positions of the Certifying Employees required by Section III.A.6;
6. a copy of GSK's Code of Conduct required by Section III.B.1;
7. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
8. (a) a copy of the letter (including all attachments) required by Section II.C.9 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements between GSK and the party

employing Third Party Personnel; and (c) a description of each entity's response to GSK's letter;

9. a summary of all Policies and Procedures required by Section III.B.3 (a copy of such Policies and Procedures shall be made available to OIG upon request);

10. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to participate in General Training and Board Member Training, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.<sup>2</sup>

11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A; (d) a summary and description of any and all current and prior engagements and agreements between GSK and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to GSK;

12. a description of the Disclosure Program required by Section III.F;

13. a description of the process by which GSK fulfills the requirements of Section III.G regarding Ineligible Persons;

14. a certification by the Compliance Officer that the notices required by Section III.N was mailed to each HCP, HCI, and Payer, the number of HCPs, HCIs and

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<sup>2</sup> In Addition to the Implementation Report, GSK shall submit to OIG by January 30, 2013 a letter containing the information specified in Section V.A.10 as it pertains to Specific Training and Management Training as required by Section III.C.

Payers to whom or which the notice was mailed, a sample copy of the notices required by Section III.N, and a summary of the calls or messages received in response to the notices;

15. a certification from the Compliance Officer that, if required under Section III.O and to the best of his/her knowledge, information regarding Payments has been posted on GSK's website as required by Section III.O;

16. a list of all of GSK's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of any each Federal health care program contractor to which GSK currently submits claims (if applicable);

17. a description of GSK's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

18. the certifications required by Section V.D.

B. Annual Reports. GSK shall submit to OIG annually a report with respect to the status of, and findings regarding, GSK's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee, the Board of Directors, the DCOs or the group of Certifying Employees described in Sections III.A.2-4 and 6;

2. a copy of the resolution by the Board required by Section III.A.3;

3. the number of individuals required to review GSK's Code of Conduct and complete the certifications required by Section III.B.1, the percentage of individuals who have completed such certifications, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

4. (a) a copy of the letter (including all attachments) required by Section II.C.9 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements between GSK and the party employing Third Party Personnel; and (c) a description of each entity's response to GSK's letter;

5. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B, including any changes to the Research and Publication Practices and Authorship-Related Practices, and the reasons for such changes (e.g., change in applicable requirements);

6. the following information regarding each type of training required by Section III.C:

a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to complete each type of training specified in Section III.C, percentage of individuals who completed the training, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

7. a summary of any significant changes to the TRACER program required by Section III.D;

8. a complete copy of all reports prepared pursuant to Section III.E, and Appendices B-C along with a copy of the IRO's engagement letters;

9. GSK's response to the reports prepared pursuant to the reviews outlined in Section III.E and Appendices B-C, along with corrective action plan(s) related to any issues raised by the reports;

10. a summary and description of any and all current and prior engagements and agreements between GSK and the IRO (if different from what was submitted as part of the Implementation Report);

GlaxoSmithKline LLC  
Corporate Integrity Agreement

11. certifications from the IRO regarding its professional independence and objectivity with respect to GSK;

12. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements (including CGMP Activities), or Government Reimbursed Products;

13. any changes to the process by which GSK fulfills the requirements of Section III.G regarding Ineligible Persons;

14. a summary of any changes to GSK's employee and executive incentive compensation and recoupment programs required by Section III.H and Appendix E and the information regarding Triggering Events and Recoupment Determinations required to be reported pursuant to Section E of Appendix E;

15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

16. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

17. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.K. This summary shall include a description of the matter and the status of the matter;

18. a summary of the FFMP and the results of the FFMP required by Section III.L, including copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that GSK took as a result of such determinations;

19. a summary of the Non-Promotional Monitoring Program and the results of the program described in Section III.M, including detailed description of any identified instances in which it was determined that the activities violated GSK's policies or that improper promotion of Government Reimbursed Products occurred and a description of

the action(s) GSK took as a result of such determinations;

20. a summary of the calls and messages received in response to the notices required by Section III.N and the disposition of those calls and messages;

21. a certification from the Compliance Officer that information regarding Payments has been posted on GSK's website as required by Section III.O;

22. a description of all changes to the most recently provided list of GSK's locations (including addresses) as required by Section V.A.16; the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers;

23. a description of any additional, updated, supplemental or changed information submitted to any Compendia in accordance with Section III.B.3.t; and a description of all arrangements, processing fees, and other payments or financial support (if any) with or made to any Compendia evaluated during the annual review described in Section III.B.3.t; and

24. the certifications required by Section V.D.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. IRO Initial Report. By March 1, 2013, GSK shall submit to OIG a report with respect to the status of, and findings regarding, the IRO Reviews for the first IRO Reporting Period (IRO Initial Report).

The IRO Initial Report shall include at a minimum:

1. a complete copy of all reports prepared pursuant to Section III.E, and Appendix B along with a copy of the IRO's engagement letters;

2. GSK's response to the reports prepared pursuant to the reviews outlined in Section III.E and Appendix B, along with corrective action plan(s) related to any issues raised by the reports;

3. a summary and description of any and all current and prior engagements and agreements between GSK and the IRO (if different from what was submitted as part of the Implementation Report);

4. certifications from the IRO regarding its professional independence and objectivity with respect to GSK;

D. Certifications.

1. Certifying Employees: In each Annual Report, GSK shall include the certifications of Certifying Employees as required by Section III.A.6;

2. Compliance Officer: In the Implementation Report, and each Annual Report, GSK shall include the following individual certification by the Compliance Officer:

a. to the best of his or her knowledge, except as otherwise described in the report, GSK is in compliance with the requirements of this CIA;

b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;

c. to the best of his or her knowledge, GSK has complied with its obligations under the Settlement Agreement: (1) not to resubmit to any Federal health care program Payers any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (2) not to charge to or otherwise seek payment from federal or state Payers for unallowable costs (as defined in the Settlement Agreement); and (3) to identify and adjust any past charges or claims for unallowable costs;

d. GSK's: (1) Policies and Procedures as referenced in Section III.B.3 above; (2) templates for standardized contracts and other similar documents; and (3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, GSK's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside GSK have been reviewed

by competent regulatory, medical, or, as appropriate, legal counsel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by GSK and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request;

e. GSK's Target Plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.j) and, for each product the Target Plans were found to be consistent with GSK's policy objectives as referenced above in Section III.B.3.j; and

f. GSK has maintained an employee and executive incentive compensation and recoupment program in accordance with the terms set forth above in Section III.H and Appendix E.

3. Certification for the IRO Initial Report: In the IRO Initial Report, GSK shall include an individual certification by the Compliance Officer that he or she has reviewed the report and has made reasonable inquiry regarding its content and believes the information in the report is accurate and truthful.

E. Designation of Information. GSK shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. GSK shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG: Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

GSK: Michael L. Shaw  
Vice President & Compliance Officer  
North America Pharmaceuticals  
GlaxoSmithKline  
Three Franklin Plaza  
200 N. 16<sup>th</sup> Street  
Philadelphia, PA 19102  
Telephone: 215.751.7337  
Facsimile: 215.751.7547

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, GSK may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

## **VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of GSK's or an applicable GSK Affiliate's books, records, and other documents and supporting

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materials and/or conduct on-site reviews of any of GSK's locations for the purpose of verifying and evaluating: (a) GSK's or an applicable GSK Affiliate's compliance with the terms of this CIA (including Appendix D); and (b) GSK's or an applicable GSK Affiliate's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements (including CGMP Activities). The documentation described above shall be made available by GSK or the applicable GSK Affiliate to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of GSK's or the applicable GSK Affiliate's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. GSK or the applicable GSK Affiliate shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. GSK's or the applicable GSK Affiliate's employees may elect to be interviewed with or without a representative of GSK or the applicable GSK Affiliate present.

#### **VIII. DOCUMENT AND RECORD RETENTION**

GSK and its Affiliates shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA (including Appendix D) until the end of 2018 (or longer if otherwise required by law) from the Effective Date.

#### **IX. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify GSK prior to any release by OIG of information submitted by GSK pursuant to its obligations under this CIA and identified upon submission by GSK as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, GSK shall have the rights set forth at 45 C.F.R. § 5.65(d).

#### **X. BREACH AND DEFAULT PROVISIONS**

GSK is expected to fully and timely comply with all of the CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, GSK and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day GSK fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board compliance obligations, including the resolution from the Board;
- d. the management accountability and certification obligations;
- e. a written Code of Conduct;
- f. written Policies and Procedures;
- g. the training of Covered Persons, Relevant Covered Persons, Management, and Board Members;
- h. a TRACER program;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;
- k. an employee and executive incentive compensation and recoupment program as required by Section III.H and Appendix E;
- l. notification of Government investigations or legal proceedings as required by Section III.I;

- m. reporting of Reportable Events as required in Section III.J;
- n. notification of written communications with FDA as required by Section III.K;
- o. a program for FFMP as required by Section III.L;
- p. a program for Non-Promotional Monitoring Program as required by Section III.M;
- q. notifications to HCPs, HCIs, and Payers as required by Section III.N; and
- r. posting of any Payments as required by Section III.O.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day GSK fails to engage and use an IRO as required in Section III.E and Appendices A-C.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day GSK fails to submit the Implementation Report or any Annual Report to OIG in accordance with the requirements of Section V of the CIA or of Appendix D by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day GSK fails to submit any IRO Review report (including the IRO Initial Report) in accordance with the requirements of Sections III.E and III.V and Appendices A-C.

5. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day GSK fails to establish and implement any of the following obligations as described in Section III of Appendix D:

- a. a GMS Compliance Officer;
- b. a GMS Compliance Committee;
- c. the Board compliance obligations, including the resolution from

the Board;

- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Manufacturing Covered Persons;
- g. cGMP Requirements;
- h. reporting of Manufacturing Reportable Events; or
- i. reporting of a recall under Section III.F of Appendix D.

6. A Stipulated Penalty of \$1,500 for each day GSK or a GSK Affiliate fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date GSK or a GSK Affiliate fails to grant access.)

7. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of GSK as part of its Implementation Report, the IRO Initial Report, or any Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

8. A Stipulated Penalty of \$10,000 for each day that GSK fails to timely submit any report required under Section III.D.3.a or III.D.3.b of Appendix D.

9. A Stipulated Penalty of \$10,000 for each lot of each Covered Product for each day that GSK fails to initiate a recall for specified lots under Section III.D of Appendix D after receipt of a Final Determination.

10. A Stipulated Penalty of \$10,000 for each lot of each Covered Product for each day that GSK fails to complete a recall within a deadline established in the Final Determination for specified lots under Section III.D of Appendix D.

11. A Stipulated Penalty of \$1,000 for each day GSK or a GSK Affiliate fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to GSK or a GSK Affiliate stating the specific grounds for its determination that GSK or a GSK Affiliate has failed to comply fully and adequately with the CIA

obligation(s) at issue and steps GSK or a GSK Affiliate shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after GSK or a GSK Affiliate receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 10 of this Section.

B. Timely Written Requests for Extensions. GSK may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after GSK fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after GSK receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that GSK has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify GSK of: (a) GSK's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, GSK shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event GSK elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until GSK cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that GSK has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by GSK to report a Reportable Event and take corrective action as required in Section III.J of the CIA or Section III.E of Appendix D;
- c. a failure to engage and use an IRO in accordance with Section III.E and Appendices A-C;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;
- e. a failure of the Board to issue a resolution in accordance with Section III.A.3 of the CIA or Section III.A.3 of Appendix D.
- f. a failure by GSK to timely initiate a recall of Covered Products sold in the United States pursuant to a Final Determination made under Section III.D of Appendix D after receipt of a Final Determination; or
- g. a failure by GSK to timely complete a recall of Covered Products sold in the United States as required in the Final Determination after receipt of the Final Determination under Appendix D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by GSK constitutes an independent basis for GSK's exclusion from participation in the Federal health care programs. Upon a determination by OIG that GSK has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify GSK of: (a) GSK's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* GSK shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. GSK is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30 day period, but that: (i) GSK has begun to take action to cure the material breach; (ii) GSK is pursuing such action with due diligence; and (iii) GSK has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, GSK fails to satisfy the requirements of Section X.D.3, OIG may exclude GSK from participation in the Federal health care programs. OIG shall notify GSK in writing of its determination to exclude GSK (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of GSK's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, GSK may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

### E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to GSK of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, GSK shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether GSK was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. GSK shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders GSK to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless GSK requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether GSK was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) GSK had begun to take action to cure the material breach within that period; (ii) GSK has pursued and is pursuing such action with due diligence; and (iii) GSK provided to OIG within that period a reasonable timetable for curing the material breach and GSK has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for GSK, only after a DAB decision in favor of OIG. GSK's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude GSK upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that GSK may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. GSK shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of GSK, GSK shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

GSK and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of GSK;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;

D. The undersigned GSK signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

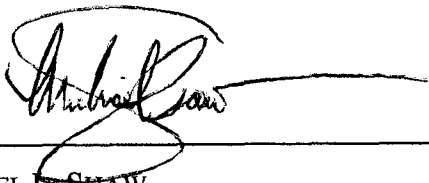
ON BEHALF OF GLAXOSMITHKLINE LLC



DEIRDRE CONNELLY  
President  
GlaxoSmithKline LLC

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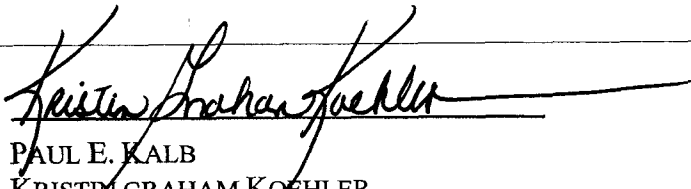
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MICHAEL L. SHAW  
Vice President & Compliance Officer  
North America Pharmaceuticals  
GlaxoSmithKline LLC

6/28/2012

DATE



PAUL E. KALB  
KRISTIN GRAHAM KOEHLER  
LAUREN K. ROTH  
Sidley Austin LLP  
Counsel for GlaxoSmithKline LLC

6/28/2012

DATE

GlaxoSmithKline LLC  
Corporate Integrity Agreement

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



GREGORY E. DEMSKE  
Chief Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services

6/22/12  
DATE



MARY E. RIORDAN  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

4/28/12  
DATE

CHRISTINA K. MCGARVEY  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

DATE

GlaxoSmithKline LLC  
Corporate Integrity Agreement

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

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GREGORY E. DEMSKE  
Chief Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services

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DATE

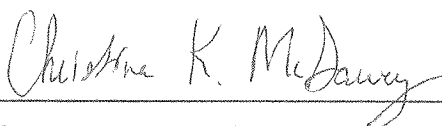
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MARY E. RIORDAN  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services


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DATE

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CHRISTINA K. MCGARVEY  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

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DATE

GlaxoSmithKline LLC  
Corporate Integrity Agreement

## **Appendix A to CIA for GlaxoSmithKline LLC**

### **Independent Review Organization**

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

#### **A. IRO Engagement.**

GSK shall engage an IRO (or IRO(s)) that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.11 of the CIA or any additional information submitted by GSK in response to a request by OIG, whichever is later, OIG will notify GSK if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, GSK may continue to engage the IRO.

If GSK engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, GSK shall submit the information identified in Section V.A.11 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by GSK at the request of OIG, whichever is later, OIG will notify GSK if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, GSK may continue to engage the IRO.

#### **B. IRO Qualifications.**

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and have expertise in applicable Federal health care program and FDA requirements that relate to the Covered IRO Functions, including expertise relating to: i) marketing and promotional activities associated with pharmaceutical products; ii) research regarding such products; and iii) publication, authorship, and disclosure activities associated with such research). The assigned individuals shall also be experienced in risk identification and mitigation in relation to pharmaceutical product marketing and promotion. The assigned individuals also shall be knowledgeable about the general requirements of the Federal health care programs under which GSK products are reimbursed;

2. assign individuals to design and select the samples for the IRO Transactions Reviews who are knowledgeable about appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each component of each IRO Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;

3. if in doubt of the application of a particular Federal health care program or FDA requirement, request clarification from the appropriate authority (e.g., CMS or FDA);

4. respond to all OIG inquiries in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendices B and C to the CIA.

D. Independence and Objectivity.

The IRO must perform the IRO Reviews in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination.

1. *GSK Termination of IRO.* If GSK terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, GSK must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. GSK must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of the termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as

described in Paragraph C, OIG may, at its sole discretion, require GSK to engage a new IRO in accordance with Paragraph A of this Appendix. GSK must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring GSK to engage a new IRO, OIG shall notify GSK of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, GSK may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with GSK prior to requiring GSK to terminate the IRO. However, the final determination as to whether or not to require GSK to engage a new IRO shall be made at the sole discretion of OIG.

## **Appendix B to CIA for GlaxoSmithKline LLC**

### **Independent Review Organization Reviews**

#### **I. Covered Functions Review, General Description**

As specified more fully below, GlaxoSmithKline (GSK) shall retain an Independent Review Organization (IRO) (or IROs) to perform reviews (IRO Reviews) to assist GSK in assessing and evaluating its systems, processes, policies, procedures, and practices related to certain of GSK's Covered Functions (collectively, "IRO Covered Functions"). The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. GSK may engage, at its discretion, a single IRO to perform both components of the IRO Review provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in GSK's systems, processes, policies, and procedures relating to the Covered IRO Functions, the IRO shall perform the Systems Review for the second and fifth IRO Reporting Periods. If GSK materially changes its systems, processes, policies, and procedures relating to the Covered IRO Functions, the IRO shall perform a Systems Review for the IRO Reporting Period(s) in which such changes were made in addition to conducting the Review for the second and fifth IRO Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each IRO Reporting Period of the CIA.

#### **II. IRO Systems Review**

##### **A. Description of Reviewed Policies and Procedures**

The Covered IRO Functions Systems Review shall be a review of GSK's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain of the Covered Functions. Where practical, GSK personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by GSK in accordance with the preceding sentence.

Specifically, the IRO shall review GSK's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

- 1) GSK's systems, processes, policies, and procedures applicable to the manner in which GSK field personnel (including sales personnel, marketing personnel, MSLs, HOLs, and personnel from the PPV group) and personnel from the Medical Affairs department (including MISs) handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved (*i.e.*, off-label) uses of Government Reimbursed Products) and the dissemination of materials relating to the uses of these products. This review shall include:
  - a) the manner in which GSK sales personnel and PPV personnel handle requests for information about off-label uses of Government Reimbursed Products (*i.e.*, by referring all such requests to Medical Affairs personnel at GSK);
  - b) the manner in which Medical Affairs personnel, including those at GSK's headquarters, handle and respond to requests for information about off-label uses of Government Reimbursed Products (including tracking the requests and using pre-approved materials for purposes of responding to the request);
  - c) the form and content of information and materials related to Government Reimbursed Products disseminated to physicians, pharmacists, or other health care professionals (collectively "HCPs"), and health care institutions (HCIs), Payers, and formulary decision-makers by GSK;
  - d) GSK's systems, processes, policies, and procedures (including the Inquiries Database) to track requests to Medical Affairs for information about off-label uses of products and responses to those requests;
  - e) the manner in which GSK collects and supports information reported in any systems used to track and respond to requests to Medical Affairs for Government Reimbursed Product information, including its Inquiries Database;

- f) the processes and procedures by which Medical Affairs, the Compliance Officer, or other appropriate individuals within GSK identify situations in which it appears that off-label or other improper promotion may have occurred; and
  - g) GSK's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;
- 2) GSK's systems, processes, policies, and procedures applicable to the manner and circumstances under which its Medical Affairs personnel (including MSLs, HOLs, or analogous personnel) participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) regarding Government Reimbursed Products and the role of the Medical Affairs personnel at such meetings or events;
- 3) GSK's systems, processes, policies, and procedures relating to GSK's internal review of promotional materials related to Government Reimbursed Products disseminated to HCPs, HCIs and Payers and individuals or entities (*e.g.*, PBMs) acting on behalf of HCPs, HCIs or government payers;
- 4) GSK's systems, policies, processes and procedures (the "Patient First Program") relating to incentive compensation for Relevant Covered Persons who are prescriber-facing sales personnel and their direct managers, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Government Reimbursed Products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that GSK establishes different methods of compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;
- 5) GSK's systems, policies, processes and procedures relating to the Executive Financial Recoupment Program described in Section III.H of the CIA and in Appendix E;

- 6) GSK's systems, processes, policies, and procedures relating to the development and review of Target Plans (as defined in Section III.B.3.j of the CIA) for Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the Target Plans based on expected utilization of Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;
- 7) GSK's systems, processes, policies, and procedures relating to Sample Distribution Policies and Procedures (as defined in Section III.B.3.k of the CIA). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from GSK (including, separately, from GSK sales representatives and other GSK personnel or components). It shall also include a review of whether samples of Government Reimbursed Products are distributed by GSK through sales representatives or are distributed from a central location and the rationale for the manner of distribution;
- 8) GSK's systems (including any centralized electronic systems), processes, policies, and procedures relating to speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;
- 9) GSK's systems, processes, policies, and procedures relating to engagement of "Consultants" (as defined in Section III.M.1 of the CIA) and all events and expenses associated with such activities;
- 10) GSK's systems, processes, policies, and procedures relating to GSK's funding, directly or indirectly, of Third Party Educational Activities for HCPs (as defined in Section II.C.8 of the CIA) and all events and expenses relating to such activities;
- 11) GSK's systems, processes, policies, and procedures relating to the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product ("Compendia"). This includes any initial submission of information to any Compendia and the submission of any

additional, updated, supplemental, or changed information, (e.g., any changes based on GSK's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia). The review shall also assess GSK's processes relating to its annual review of all arrangements, processing fees, or other payments or financial support (if any) provided to any Compendia;

12) GSK's systems, processes, policies, and procedures relating to Research and Publication Practices (as defined in Section III.B.3.u of the CIA), including the decision to provide financial or other support for such Research; the manner in which Research support is provided; the publication of information about the Research, including the publication of information about the Research results and trial outcomes, and uses made of publications relating to such research;

13) GSK's systems, processes, policies and procedures relating to authorship of any journal articles or other publications about GSK-Sponsored Research or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all financial relationships between the author and GSK, the identification of all authors or contributors (including professional writers, if any) associated with a given publication, and the scope and breadth of research results made available to each author or contributor;

14) GSK's systems, policies, processes, and procedures applicable to the manner and circumstances under which GSK personnel (including sales personnel (if any), personnel from the PPV Unit, MSLs, HOLs, or analogous personnel) participate in meetings with Payers (as defined in Section II.C.6 of the CIA) regarding Government Reimbursed Products and the role of the GSK personnel at such meetings; and

15) the form and content of information and materials disseminated by GSK to Payers and GSK's systems, policies, processes, and procedures relating to GSK's internal review and approval of information and materials related to Government Reimbursed Products disseminated to Payers by GSK.

## B. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of GSK's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-15 above, including a general description of GSK's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
- 3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-15 above are made known or disseminated within GSK;
- 4) a detailed description of any system(s) used to track and respond to requests for information about Government Reimbursed Products (including the Inquiries Database);
- 5) findings and supporting rationale regarding any weaknesses in GSK's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
- 6) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

### III. IRO Transactions Review

As described more fully below in Sections III.A-F, the Transactions Review for the second through sixth IRO Reporting Periods shall include: (1) a review of a sample of Inquiries reflected in the Inquiries Database; (2) a review of GSK's Target Plans and GSK's Target Plan review process; (3) a review of Sampling Events as defined below in Section III.C; (4) a review of records relating to a sample of the Payments that are reported by GSK pursuant to Section III.O of the CIA; (5) a review of Research and Publication Practices and Authorship-Related Practices; and (6) a review of up to three additional items identified by the OIG in accordance with Section III.E.1.b of the CIA

(hereafter “Additional Items”). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

For purposes of the Transactions Review for the first IRO Reporting Period, the Transactions Review shall include a review of Items 1-3 outlined in the preceding paragraph. The Transaction Review Report for the first IRO Reporting Period shall report on Items 1-3 in accordance with Section III.G below.

A. Review of Inquiries and Inquiries Database

1) Description of Inquiries Database

As set forth in Section III.B.3.g of the CIA, GSK shall establish a database to track information relating to requests for information received by GSK about its Government Reimbursed Products (hereafter “Inquiries”). Specifically, GSK shall document and record all Inquiries received from HCPs or HCIs regarding Government Reimbursed Products in a database(s) (the “Inquiries Database”). GSK shall record in the Inquiries Database the following information for each Inquiry received: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, medical information request form); 3) name of requesting HCP or HCI or other individual or entity; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about an off-label indication for the product; 6) nature/form of the response from GSK (including a record of any materials provided in response to the request); and 7) the name of the GSK representative who called upon or interacted with the HCP or HCI.

2) Internal Review of Inquiries Database

On a semi-annual basis, the Compliance Officer or designee shall review the Inquiries Database and related information, as appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters (“Inquiry Report”). The Compliance Officer or designee shall review the Inquiry Reports to assess whether the information contained in the report suggests that improper off-label promotion may have occurred in connection with any Inquiry(ies). If the Compliance Officer or designee, in consultation with other appropriate GSK personnel, suspects that improper off-label promotion may have occurred in connection with any Inquiry, the

Compliance Officer or designee shall undertake a follow-up review of the Inquiry (Off-Label Review), make specific findings based on his/her Off-Label Review, and take all appropriate responsive action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.J of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of 50 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period. Forty of the Inquiries reviewed by the IRO shall be Inquiries for which GSK conducted an Off-Label Review, and the other ten shall be Inquiries for which GSK did not conduct an Off-Label Review. For each Inquiry reviewed, the IRO shall determine:

- a) Whether each item of information listed above in Section III.A.1 is reflected in the Inquiries Database for each reviewed Inquiry; and
- b) For each Inquiry for which the Compliance Officer conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by GSK based on the Off-Label Review findings.

B. IRO Review of GSK's Target Plans and Target Plan Review Process

The IRO shall conduct a review and assessment of GSK's review of its Target Plans for Government Reimbursed Products as set forth in Section III.B.3.j of the CIA. GSK shall provide the IRO with: i) a list of Government Reimbursed Products promoted by GSK during the IRO Reporting Period; ii) information about the FDA-approved uses for each such product; and iii) the Target Plans for each such product. GSK shall also provide the IRO with information about the reviews of Target Plans that GSK conducted during the relevant IRO Reporting Period and any modifications to the Target Plans made as a result of GSK's reviews.

For each Target Plan, the IRO shall select a sample of 50 of the HCPs and HCIs included on the Target Plan. For each Target Plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by GSK

in conducting its review and/or modifying the Target Plan. The IRO shall seek to determine whether GSK followed its criteria and Policies and Procedures in reviewing and modifying the Target Plan.

The IRO shall note any instances in which it appears that the sampled HCPs or HCIs on a particular Target Plan are inconsistent with GSK's criteria relating to the Target Plan and/or GSK's Policies and Procedures. The IRO shall also note any instances in which it appears that GSK failed to follow its criteria or Policies and Procedures.

C. IRO Review of the Distribution of Samples of GSK Government Reimbursed Products

The IRO shall conduct a review and assessment of the distribution of samples of Government Reimbursed Products to HCPs and HCIs. GSK shall provide the IRO with: i) a list of Government Reimbursed Products for which GSK distributed samples during the IRO Reporting Period; ii) information about the FDA-approved uses for each such product; and iii) information about GSK's Sample Distribution Policies and Procedures, including GSK's exclusion lists showing which types of samples may not be distributed by sales personnel or other GSK personnel to HCPs and HCIs of particular medical specialties or types of clinical practices. GSK shall also provide the IRO with information about the reviews of Sample Distribution Policies and Procedures that GSK conducted during the IRO Reporting Period as set forth in Section III.B.3.k of the CIA and any modifications to the Sample Distribution Policies and Procedures or exclusion lists made as a result of GSK's reviews.

For each Government Reimbursed Product for which GSK distributed samples during the IRO Reporting Period, the IRO shall randomly select a sample of 50 separate instances in which GSK provided samples of the product to HCPs or HCIs. Each such instance shall be known as a "Sampling Event."

For each Sampling Event, the IRO shall review all documents and information relating to the distribution of the sample to the HCP or HCI. The reviewed materials shall include materials about the following: 1) the quantity, dosage, and form of the GSK product provided to the HCP or HCI; 2) the identity and type of medical specialty or clinical practice of the HCP or HCI; 3) which individual GSK sales personnel or other GSK personnel provided the sample to the HCP or HCI; and 4) the manner and mechanism through which the sample was requested (e.g., sample request form, letter, or call to GSK).

For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the Government Reimbursed Product approved by the FDA and whether the sample was distributed by an GSK representative in a manner consistent with GSK's sample distribution policy for the product(s) provided during the Sampling Event. To the extent that a sample was provided to an HCP or HCI by a GSK representative other than a sales personnel, the IRO shall contact the HCP or HCI by letter. The letter shall request that the HCP or HCI: 1) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; 2) verify that he/she/it requested the samples provided during the Sampling Event; 3) explain or confirm its type of medical specialty or clinical practice; and 4) identify the basis for requesting the sample (e.g., conversations with a GSK sales representative, conversation with a GSK representative at headquarters, independent research, or knowledge of the HCP or HCI).

For each Sampling Event, the IRO shall compare the medical specialty and type of clinical practice of the HCPs and HCIs that received the sample with uses of the Government Reimbursed Product approved by the FDA. The IRO shall note any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the Government Reimbursed Product approved by the FDA. For each such situation, the IRO shall note the process followed by GSK in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination. The IRO shall also note any instances in which it appears that GSK failed to follow its Sample Distribution Policies and Procedures for the Government Reimbursed Product(s) provided during the Sampling Event.

#### D. IRO Review of Physician Payment Listings

##### 1. Information Contained in Physician Payment Listings

For purposes of the IRO review as set forth in this Section III.D, each annual listing of physicians and Related Entities who received Payments (as defined in Section III.O of the CIA) from GSK shall be referred to as the "Physician Payment Listing" or "Listing." For each physician and Related Entity, each Physician Payment Listing shall include the following information: i) physician's full name; ii) name of Related Entity (if applicable); iii) city and state of the physician's practice or the Related Entity; and (iv) the aggregate value of the Payment(s) in the preceding year(s).

For purposes of this IRO review, the term "Control Documents" shall include all documents or electronic records associated with each Payment reflected in the Physician

Payments Listing for a sampled physician and/or Related Entity. For example, the term “Control Documents” includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the Listing; contracts relating to the Payment(s) reflected in the Listing; documents relating to the occurrence of Payment(s) reflected in the Listing; documents reflecting any work product generated in connection with the Payment(s); documents submitted by field personnel or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

## 2. Selection of Sample for Review

For each IRO Reporting Period, the OIG shall have the discretion to identify up to 50 physicians or Related Entities from the applicable Physician Payment Listing that will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO at least 90 days prior to the end of the IRO Reporting Period, of the physicians and/or Related Entities subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 physicians and/or Related Entities to be included in the review. For each selected physician and/or Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in the Listing identified by the IRO as necessary and sufficient to validate the Payment information in the Listing.

## 3. IRO Review of Control Documents for Selected Physicians and/or Related Entities

For each physician and/or Related Entity selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:

- a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;
- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in GSK’s policies;
- c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician is consistent with the

value of the Payments(s) reflected in the Control Documents;  
and

- d) Whether the Control Documents reflect that GSK's policies were followed in connection with Payment(s) reflected in the Listing (e.g., all required written approvals for the activity were obtained in accordance with GSK's policies).

4. Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:
  - i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
  - ii. the IRO cannot confirm that GSK otherwise followed its policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, including its policies and procedures relating to any Payment(s) reflected in the Listing; or
- b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with GSK's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but GSK has initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that GSK otherwise followed its policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

E. IRO Review of Research and Publications Practices and Authorship-Related Activities

The IRO shall conduct a review and assessment of GSK's Research and Publications Practices and Authorship-Related Activities as described in Sections III.B.3. u-v of the CIA.

Review of Research Activities: GSK shall provide the IRO with a list of all Research activities (as defined in Section III.B.3.u of the CIA) that were "active" (as classified in GSK's tracking system) during the IRO Reporting Period, and the IRO shall select a sample of 40 such activities, which sample shall include a review of each type of Research (*i.e.*, GSK-Sponsored post-marketing clinical trials, other GSK-Sponsored post-marketing studies, and post-marketing investigator-sponsored studies (ISSs).) The IRO shall review samples of each type of Research in proportion to the relative number of each type of Research that occurred during the reporting period. GSK shall provide the IRO with documents relating to the Research activities sufficient for the IRO to conduct the reviews outlined below.

For each sampled Research activity, the IRO will review whether: (i) the activity was approved consistent with GSK's standards, policies, procedures and processes regarding sponsorship or support of Research, including obtaining required approval for the Research by GSK's medical and/or research organizations and ensuring that the Research was conducted for the purpose of fostering increased understanding of scientific, clinical or medical issues; (ii) there is an executed written agreement with the Researcher that meets the requirements of GSK's standards, policies and procedures and, among other things, requires the Researcher to disclose in any publication of Research, GSK's support and any financial interest the researcher may have in GSK; and (iii) GSK's sales, marketing, or other commercial personnel did not participate in the design, conduct, or publication of the Research activity except as permitted under the limited exceptions in GSK's policies and procedures.

Review of Publication Activities:

GSK shall provide the IRO with a list of publication activities (as defined in Section III.M.3 of the CIA) that resulted in publication of data from GSK-Sponsored post-marketing clinical trials or post-marketing studies of Government Reimbursed Products that appeared during the IRO Reporting Period. The list will be broken down into two categories: (i) GSK-Sponsored post-marketing clinical trials, and (ii) other GSK-Sponsored post-marketing studies (*e.g.*, observational studies, health outcomes studies, epidemiology studies, and meta-analyses and pooled analyses.) The IRO shall select a sample from each category for review, in proportion to the relative numbers in each category (collectively, “Reviewed Publication Activities”). The IRO shall review a total of 60 Reviewed Publication Activities. GSK shall provide the IRO with copies of the publications and documents and information relating to each of the Reviewed Publication Activities sufficient for the IRO to conduct the reviews outlined below.

The IRO will assess each of the Reviewed Publication Activities to test whether the Reviewed Publication Activity was conducted in a manner consistent with GSK’s standards, policies, procedures and processes, including those that require: i) posting of summary results from all GSK-Sponsored post-marketing interventional research studies of Government Reimbursed Products on GSK’s Clinical Study Register within a specified periods of time; ii) posting of summaries of study protocols for such research studies in the GSK Clinical Study Register; iii) registration of summary results from applicable GSK-Sponsored clinical trials on the NIH sponsored website in compliance with all Federal requirements; iv) publication (or attempted publication) of the results of GSK-Sponsored post-marketing interventional Research studies in peer-reviewed journals within specified periods of times; and v) compliance with GSK’s operating practices regarding publications relating to GSK-Sponsored post-marketing interventional research studies of Government Reimbursed Products (including standards relating to appropriateness, accuracy, balance, and acknowledgement of GSK’s role as the funding source for the Research).

#### Review of Authorship-Related Activities:

For each of the Reviewed Publication Activities, the IRO shall also assess the activity to test whether the activity was conducted in a manner consistent with GSK’s standards, policies, procedures and processes relating to authorship, including those that require: i) authors of journal articles about GSK-Sponsored Research to adhere to ICMJE authorship requirements (except in instances in which a particular journal requires an alternative procedure); ii) authors of articles on GSK-Sponsored Research to disclose any GSK financial support for the study and any financial relationship with GSK; iii) authors of a GSK publication of GSK-Sponsored Research to make substantial contributions to the study and give final approval to the version of the publication ultimately published;

and iv) certifications from employees and medical writing contractors as to any GSK publication of GSK-Sponsored Research on which the individual is listed as an author or contributor.

#### F. IRO Review of Additional Items

As set forth in Section III.E.1.b of the CIA, for the second through sixth IRO Reporting Periods, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter “Additional Items”). No later than 150 days prior to the end of the applicable IRO Reporting Period, the OIG shall notify GSK of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or GSK shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO’s findings based on its review for each Additional Item; and the IRO’s recommendations for any changes in GSK’s systems, processes, policies, and procedures based on its review of each Additional Item).

GSK may propose to the OIG that its internal audit(s) be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable IRO Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow GSK’s internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of GSK’s planned internal audit work, the results of the Transactions Review(s) during prior IRO Reporting Period(s), and GSK’s demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies GSK’s request to permit its internal audit work to be substituted for a portion of the IRO’s review of Additional Items in a given IRO Reporting Period, GSK shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of GSK’s internal audit work for a given IRO Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review,

the IRO shall review at least 20% of the sampling units reviewed by GSK in its internal audits.

G. Transactions Review Report

For each IRO Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

- 1) General Elements to Be Included in Report
  - a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
  - b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
  - c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

2) Results to be Included in Report

Consistent with the scope of items reviewed by the IRO for the applicable IRO Reporting Period, the following results shall be included in each Transaction Review Report:

(Relating to the Review of Inquiries)

- a) in connection with the review of Inquiries, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (e.g., the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;
- b) for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the Inquiries Database;

- c) for each Inquiry sample unit, findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the Inquiries Database; and (ii) for each Inquiry for which an Off-Label Review was conducted, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by GSK as a result of the Compliance Officer's findings;
- d) the findings and supporting rationale regarding any weaknesses in GSK's systems, processes, policies, procedures, and practices relating to the Inquiries, and the Inquiries Database, if any;
- e) recommendations for improvement in GSK's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

(Relating to the Target Plan Reviews)

- f) a list of the Government Reimbursed Products promoted by GSK during the IRO Reporting Period and a summary of the FDA-approved uses for such products;
- g) for each Government Reimbursed Product which was promoted during the IRO Reporting Period: i) a description of the criteria used by GSK in developing or reviewing the Target Plans and for including or excluding specified types of HCPs or HCIs from the Target Plans; ii) a description of the review conducted by GSK of the Target Plans and an indication of whether GSK reviewed the Target Plans as required by Section III.B.3.j of the CIA; iii) a description of all instances for each Target Plan in which it appears that the HCPs and HCIs included on the Target Plan are inconsistent with GSK's criteria relating to the Target Plan and/or GSK's Policies and Procedures; and iv) a description of all instances in which it appears that GSK failed to follow its criteria or Policies and Procedures relating to Target Plans or the review of the Target Plans;
- h) the findings and supporting rationale regarding any weaknesses in GSK's systems, processes, policies, procedures, and practices

relating to GSK's Target Plans or the review of the Target Plans, if any;

- i) recommendations, if any, for changes in GSK's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to Target Plans or the review of the Target Plans;

(Relating to the Sampling Event Reviews)

- j) for each Government Reimbursed Product distributed during the IRO Reporting Period: i) a description of Sample Distribution Policies and Procedures (including whether sales representatives may provide samples for the product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice a sales representative may provide samples); ii) a detailed description of any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event was not consistent with the uses of the product approved by the FDA. This description shall include a description of the process followed by GSK in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and iii) a detailed description of any instances in which it appears that GSK failed to follow its Sample Distribution Policies and Procedures for the Government Reimbursed Product(s) provided during the Sampling Event;
- k) the findings and supporting rationale regarding any weaknesses in GSK's systems, processes, policies, procedures, and practices relating to GSK's distribution of samples of Government Reimbursed Products, if any;
- l) recommendations, if any, for changes in GSK's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples;

(Relating to the Physician Payment Listing Reviews)

- m) a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;
- n) for each sampled physician or Related Entity, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable GSK policy; (iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that GSK's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (v) disciplinary action was undertaken in those instances in which GSK policies were not followed;
- o) for each sampled physician or Related Entity unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action;
- p) if any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

(Relating to the Review of Research and Publication Practices and Authorship-Related Activities)

- q) a description of each sampled Research activity reviewed, including an identification of the types of documents and information reviewed in connection with each sampled Research activity;
- r) an assessment of whether, for each sampled Research activity: (i) the activity was approved consistent with GSK's standards, policies, procedures and processes regarding sponsorship or support of Research; (ii) there is an executed written agreement with the

Researcher that meets the requirements of GSK's standards, policies and procedures; and (iii) GSK's sales, marketing, or other commercial personnel did not participate in the design, conduct, or publication of the Research Activity except as permitted under GSK's policies and procedures. If a sampled Research activity failed to meet GSK standards, policies, procedures and processes, an explanation of the deficiency;

- s) a description of each Reviewed Publication Activity assessed by the IRO, including an identification of the types of documents and information reviewed in connection with each Reviewed Publication Activity;
- t) an assessment of whether for each Reviewed Publication Activity; i) authors of journal articles about GSK-Sponsored Research adhered to ICMJE requirements; ii) authors of articles about GSK-Sponsored Research disclosed any GSK financial support for the study and any financial relationship with GSK; iii) authors of a GSK publication about GSK-Sponsored Research made substantial contributions to the study and gave final approval to the version of the publication ultimately published; and iv) GSK obtained certifications from employees, medical writing contractors, and outside authors as to any GSK publication of GSK-Sponsored Research on which the individual is listed as an author or contributor;
- u) an assessment of whether for each Reviewed Publication Activity; i) authors of journal articles about GSK-Sponsored Research adhered to ICMJE requirements; ii) authors of articles on GSK-Sponsored Research disclosed any GSK financial support for the study and any financial relationship with GSK; iii) authors of a GSK publication of GSK-Sponsored Research made substantial contributions to the study and gave final approval to the version of the publication ultimately published; and iv) GSK obtained certifications from employees, medical writing contractors, and outside authors as to any GSK publication of GSK-Sponsored Research on which the individual is listed as an author or contributor;
- v) if any Reviewed Publication Activity failed to meet GSK standards, policies, procedures and processes, an explanation of the deficiency;

- w) the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in GSK's systems, processes, policies, procedures, and practices relating to GSK's Research and Publications Practices and Authorship-Related Activities, if any;
- x) recommendations, if any, for changes in GSK's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to Research and Publications Practices and Authorship-Related Activities;

(Relating to the Review of Additional Items)

- y) for each Additional Item reviewed, a description of the review conducted;
- z) for each Additional Item reviewed, the IRO's findings based on its review;
- aa) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in GSK's systems, processes, policies, procedures, and practices relating to the Additional Item, if any;
- bb) for each Additional Item reviewed, recommendations, if any, for changes in GSK's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

**Appendix C to CIA for GlaxoSmithKline LLC**  
**IRO Reviews of GSK's Targeted Risk Analysis and**  
**Compliance Evaluation Review (TRACER) Program**

I. General Description of TRACER program

GSK uses the Targeted Risk Analysis and Compliance Evaluation Review process (TRACER) as a tool to evaluate and mitigate promotional risks (hereinafter, "risks") associated with all prescription Government Reimbursed Products that have field force support in the United States (GSK Products).

*1. Risk Identification and Evaluation*

As part of TRACER, risk information will be solicited from four key sources: (i) Copy Approval Teams; (ii) U.S. Pharma's Monitoring Control Center of Excellence (CCoE); (iii) Deputy Compliance Officers (DCOs); and (iv) Legal department personnel.

Based on inputs from these sources, a relative risk ranking report will be produced for all GSK Products (Risk Evaluation Report). The Risk Evaluation Report will be presented to the leadership team of each U.S. Pharma commercial business unit (Leadership Team) and the U.S. Pharma Commercial Leadership Team (CLT) along with recommendations regarding which products may require enhanced risk mitigation plans.

The Risk Evaluation Report will also be used by the CCoE to inform the risk-based selection of products as required by the Field Force Monitoring Program described in CIA Section III.L.

*2. Risk Mitigation Plans*

Risk Mitigation Plans (RMPs) will be completed annually for all GSK Products. All RMPs will outline standard risk mitigation activities that will be performed and tracked for each GSK Product, regardless of the product's relative risk ranking (Standard RMPs). Standard risk mitigation activities will consist of the monitoring activities to be conducted for each GSK Product in the upcoming year, such as monitoring of speaker programs, speaker training, advisory boards, sampling, verbatim reviews, medical information requests and ride-alongs with sales personnel.

Based on the Risk Evaluation Report, products may be selected for Enhanced RMPs by either (or both) the Leadership Teams and the CLT. These RMPs will include enhanced risk mitigation activities, in addition to the standard activities (Enhanced RMPs). Enhanced RMPs will consist of activities tailored to the risks identified during the risk ranking process. For example, such activities may include increased compliance

messaging from Leadership Teams, modifications to or limitations of promotional programs, or enhanced training requirements.

All RMPs (whether Standard or Enhanced) will be developed by brand teams, in consultation with their respective DCOs and the CCoE, on an annual basis. Each RMP will specify the: (i) risk monitoring activities; (ii) metrics by which monitoring activities and results will be evaluated and/or measured; (iii) risk mitigation action items, if necessary; (iv) metrics by which risk mitigation activities and results will be evaluated and/or measured; (v) responsible individual(s); and (vi) expected date(s) of monitoring and/or action item completion. The RMPs will be reviewed and approved by the respective business unit Leadership Teams.

### 3. *Risk Mitigation Plan Tracking*

RMP activities (including risk monitoring activities, risk mitigation activities, and risk mitigation action items) will be tracked by the CCoE and reported using a Monitoring Dashboard which will identify risk monitoring and mitigation activities and track their progress on at least a quarterly basis. The status of the RMPs will be tracked and reported to Leadership Teams and compliance personnel on at least a quarterly basis.

## II. TRACER Reviews, General Description

A. As specified more fully below, GSK shall retain an IRO to assist GSK in assessing and evaluating its systems, processes, policies, procedures, and practices relating to the TRACER program (TRACER Review). The TRACER Review shall consist of two components - a systems review (TRACER Systems Review) and a transactions review (TRACER Transactions Review) as described more fully below. GSK may engage, at its discretion, a single IRO to perform both components of the TRACER Review provided that the entity has the necessary expertise and capabilities to perform both.

B. If there are no material changes in GSK's systems, processes, policies, and procedures relating to TRACER, the IRO shall perform the TRACER Systems review for the second and fifth IRO Reporting Periods. If GSK materially changes its systems, processes, policies, and procedures relating to TRACER, the IRO shall perform a TRACER Systems Review for the IRO Reporting Period(s) in which such changes were made in addition to conducting the Systems Review for the second and fifth IRO Reporting Periods. The additional TRACER Systems Review(s) shall consist of: (1) an identification of the material changes; (2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and (3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the TRACER Transactions Review for second through sixth IRO Reporting Periods of the CIA.

### III. TRACER Systems Review

#### A. The TRACER Systems review shall consist of the following:

1. A review of the processes by which GSK develops and evaluates Risk Evaluation Reports and develops Standard and Enhanced RMPs, including the sources of information (e.g., the individual personnel, departments or functional areas, and/or any systems involved) used to compile the Reports and RMPs; the types of underlying data and information that are considered or evaluated during the development of the Risk Evaluation Reports and the RMPs; and the timing for development of Risk Evaluation Reports and the RMPs (including modifications to the Reports or RMPs in the event of significant new developments);
2. An assessment of whether, in developing the Risk Evaluation Reports and the RMPs: i) additional or different sources of information; ii) additional or different types of data or information; and iii) additional or different timing cycles should be utilized;
3. A review of the experience and background of the brand directors responsible for development of the RMPs and an assessment of the completeness and appropriateness of the training, policies, procedures, standard operating procedures, and guidance such individuals receive regarding the development of the RMPs;
4. An assessment of whether the standard risk mitigation activities (monitoring activities) included in RMPs are designed to: (i) adequately monitor all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iii) ensure that the activity associated with an identified risk does not occur in the future;
5. An assessment of whether standard risk mitigation activities (monitoring activities) that may be included in RMPs should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific products reviewed;

6. An assessment of whether enhanced risk mitigation activities and risk mitigation action items (and options for such activities) included in Enhanced RMPs are designed to: (i) adequately address all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iii) ensure that the activity associated with an identified risk does not occur in the future;
7. An assessment of whether enhanced risk mitigation activities that may be included in RMPs should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific products reviewed; and
8. A review of the systems, policies, procedures, and processes (including the Monitoring Dashboard and any narrative supplements) by which GSK tracks and manages RMP activities and an assessment of whether the systems, policies, procedures and processes ensure that the RMPs are appropriately implemented (including by identifying individuals responsible for the follow-up or action items).

B. The IRO shall prepare a report based upon each Systems Review performed (System Review Report). The Systems Review Report will include the IRO's findings, recommendations, observations, and comments on items 1-8 above and, to the extent not otherwise addressed, an assessment of the following: (i) whether the Risk Evaluation Reports and RMPs identify and prioritize relevant risks; (ii) whether the risk monitoring activities, risk mitigation activities and any risk mitigation action items identified in RMPs address identified risks; (iii) whether sufficient controls exist to ensure that all risk mitigation steps (including monitoring activities and risk mitigation activities) are completed in accordance with the RMPs; iv) whether the options for risk monitoring activities and risk mitigation activities identified in the RMPs address and potentially mitigate identified risks; and (iv) whether sufficient controls exist to ensure that all agreed-upon risk monitoring activities and risk mitigation activities are completed in accordance with the RMPs.

#### IV. TRACER Transactions Review

A. At least thirty (30) days prior to the end of the second through sixth IRO Reporting Periods, GSK shall submit to OIG a list of all GSK Products for which RMPs were developed. GSK shall notify the OIG about which products had Standard RMPs and which products had Enhanced RMPs. Prior to the end of the applicable IRO

Reporting Period, OIG shall select 3 GSK Products (each a “Selected Product” and together the “Selected Products”) to be reviewed in connection with the TRACER Transactions Review.

B. For each IRO Reporting Period and for each Selected Product, the IRO shall conduct a review of: i) the applicable Risk Evaluation Report entry and RMP; ii) documents and materials related to the development of the RMP; and iii) documents and materials relating to the implementation of the RMP (including the Monitoring Dashboard and any supplements to the Scorecard). The IRO shall also interview the brand team director responsible for the development of the RMP and the individual(s) responsible for the implementation of the risk monitoring and risk mitigation activities specified in the RMP.

The objective of the IRO shall be to: (i) understand the processes followed by GSK in developing the RMP for each Selected Product, including the underlying bases for GSK’s decision to develop either a Standard RMP or an Enhanced RMP for the Selected Product; (ii) determine whether, based on the information contained in the Risk Evaluation Report, an appropriate RMP (including as to the included risk monitoring activities, risk mitigation activities, and risk mitigation action items) was developed for the Selected Product; and (iii) assess GSK’s implementation and tracking of the implementation of the RMP for the Selected Product.

C. The IRO will prepare a report based on each TRACER Transactions Review performed (Transactions Review Report). The Transactions Review Report shall include the following:

1. an identification of the 3 Selected Products and a description of the documents and information reviewed in connection with each Selected Product, including a description of whether the RMP for each Selected Product was a Standard RMP or an Enhanced RMP,
2. for each Selected Product, a description of: i) the process followed in developing the RMP; and ii) the types of identified risks associated with the Selected Product;
3. for each Selected Product, an assessment of whether it was appropriate for GSK to develop, as applicable, an Enhanced or a Standard, RMP for the product;
4. for each Selected Product, an assessment of whether, based on the information contained in the Risk Evaluation Report, an appropriate RMP was developed for the Selected Product;

5. for each Selected Product, a description of the expertise and backgrounds of the brand directors who were responsible for the development of the RMP;
6. for each Selected Product, a description of the following items set forth in the RMP: (i) risk monitoring activities; (ii) metrics by which the risk monitoring activities and results will be evaluated and/or measured; (iii) risk mitigation activities, including any risk mitigation action items; (iv) metrics by which the risk mitigation activities and results will be evaluated and/or measured; (v) responsible individual(s); (vi) expected date(s) of completion for each risk monitoring activity and risk mitigation activity; and (vii) if the RMP did not specify each of the items set forth above, a description of any deficiencies;
7. for each Selected Product, a description of whether risk monitoring activities specified in the RMP were implemented and tracked in accordance with the RMP and GSK's policies and procedures, and a description of any deficiencies;
8. for each Selected Product, a description of whether risk mitigation activities (including any action items) specified in the RMP were implemented and tracked in accordance with the RMP and GSK's policies and procedures, and a description of any deficiencies;
9. for each Selected Product a description of: (i) any recommendations made by the IRO regarding the RMP or any risk monitoring activities and risk mitigation activities included in the RMP; (ii) whether, and in what manner, GSK implemented the recommendations from the IRO; and (iii) if GSK did not implement the IRO recommendations, a description of the rationale for GSK's decision not to implement the recommendations; and
10. the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in GSK's systems, processes, policies, procedures, and practices relating to the TRACER program, if any; and recommendations, if any, for changes in GSK's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the TRACER program.

## **Appendix D to CIA for GlaxoSmithKline LLC**

### **Global Manufacturing and Supply-Related Provisions**

#### **I. PREAMBLE**

Prior to the Effective Date of the CIA (as defined below), GSK and its Affiliates established a voluntary compliance program applicable to the Global Manufacturing and Supply business unit (GMS Compliance Program). GMS has responsibility for the compliance function at the manufacturing facility located in Zebulon, North Carolina (Zebulon) and at manufacturing facilities worldwide. GMS employees at Zebulon are responsible for the release and post-release management of all Covered Products (defined below in Section II.C.3) distributed in the United States that are either manufactured at the Zebulon site or manufactured at other manufacturing facilities operated by GMS and located outside of the United States.

The GMS Compliance Program includes a GMS Compliance Officer and a GMS Compliance Committee. The GMS Compliance Program also includes a Code of Conduct (as described in Section III.B.1 of the CIA), written policies and procedures, educational and training initiatives, a Disclosure Program that allows for the confidential disclosure and investigation of potential compliance violations and disciplinary procedures, screening measures for Ineligible Persons, and internal auditing procedures. GSK shall continue the GMS Compliance Program throughout the term of this Appendix and shall do so in accordance with the terms set forth below. GSK may modify its GMS Compliance Program as appropriate, but, at a minimum, GSK shall ensure that during the term of this Appendix, it shall comply with the obligations set forth in this Appendix.

#### **II. TERM AND SCOPE OF THIS APPENDIX**

A. Unless otherwise specified, the period of the compliance obligations assumed by GSK and its Affiliates under this Appendix D shall be five reporting periods, as defined below. The “Effective Date” shall be the date on which the final signatory of the CIA executes the CIA. The first Reporting Period shall be from the Effective Date through December 31, 2013. The second and subsequent Reporting Periods shall be from January 1 through December 31 of each of the subsequent four calendar years.

B. Sections III.D of this Appendix to the CIA and sections VII, X, and XI of the CIA shall expire no later than 120 days after OIG’s receipt of: (1) GSK’s final Annual Report with respect to this Appendix; or (2) any additional materials submitted by GSK pursuant to OIG’s request, whichever is later.

C. The scope of this Appendix shall be governed by the following definitions:

1. “Manufacturing Covered Persons” includes:

- a. President, Global Manufacturing and Supply;
- b. All members of the GMS Executive Team;
- c. Senior Vice President of GMS Quality;
- d. All members of the Quality Executive Team (QET);
- e. All “above-site” employees with a direct reporting line into a QET member, and whose responsibilities include managing GMS employees that directly support cGMP Activities at the Covered Manufacturing Facility(ies);
- f. The Site Quality Director at the Covered Manufacturing Facility(ies);
- g. All GSK employees at the Covered Manufacturing Facility(ies) who are engaged in cGMP Activities;
- h. Senior Vice President of GMS Pharma Operations;
- i. All above-site employees with a direct reporting line to the Senior Vice President of Pharma Operations whose responsibilities include managing manufacturing operations at the Covered Manufacturing Facility(ies);
- j. With respect to GMS manufacturing facilities (other than a Covered Manufacturing Facility) located in the United States that manufacture and/or release drug products for distribution in the United States, the Site Director, the Site Quality Director, and any employee who is directly responsible for authorizing the release for distribution of drug products at such GMS manufacturing facilities;
- k. With respect to GSK vaccines manufacturing facilities (other than a Covered Manufacturing Facility) located in the United States that manufacture and/or release vaccines for distribution in the United States, the Site Director, the Site Quality Director and any employee who is directly responsible for authorizing the release for distribution of vaccines at such vaccines manufacturing facilities;
- l. Any GSK employee at a distribution center located in the United States that is operated by or on behalf of GSK who is directly responsible for authorizing the release for distribution of drug products or vaccines from such distribution center; and
- m. Any contractor, subcontractor, agent or other person whose normal place of work is a Covered Manufacturing Facility(ies) and whose day-to-day responsibilities directly relate to cGMP Activities.

Notwithstanding the above, this term does not include employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per calendar year, except that any such individuals shall become “Manufacturing Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “cGMP Activities” means activities directly related to ensuring compliance with current Good Manufacturing Practice (cGMP) requirements contained in the Federal Food, Drug, and Cosmetic Act and applicable regulations (collectively “cGMP Requirements”), to submitting cGMP-related reports and information to the FDA, and/or responding to FDA inspectional observations or other correspondence, including correspondence regarding cGMP Requirements.

3. “Covered Products” means prescription drug products sold by GSK that are reimbursed by a Federal health care program and that are manufactured at a GSK facility and released by a Covered Manufacturing Facility (as defined below in Section II.C.4) or any other GSK facility for distribution into the United States. Vaccines are not Covered Products.

4. “Covered Manufacturing Facility” means the GSK facility in Zebulon, North Carolina, and subject to Section IV.A, any other GSK facility that after the Effective Date of this CIA and Appendix, manufactures, or is responsible for the release of Covered Products in the United States.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

To the extent not accomplished prior to the Effective Date, GSK shall establish and maintain a GMS Compliance Program that includes the following elements:

#### **A. Compliance Officer and GMS Compliance Committee**

1. *Compliance Officer.* Prior to the Effective Date, GSK appointed an individual to serve as a Compliance Officer for its GMS business unit (GMS Compliance Officer) and GSK shall maintain a GMS Compliance Officer for the term of this Appendix. The GMS Compliance Officer shall be responsible for overseeing the development and implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Appendix relating to cGMP Activities, with applicable Federal health care program requirements and applicable FDA requirements. The GMS Compliance Officer shall be a member of senior management of GMS, and shall report directly to the Senior Vice President for Governance, Ethics and Assurance of GlaxoSmithKline PLC, who, in turn reports to the Chief Executive Officer of GlaxoSmithKline PLC. The GMS Compliance Officer shall make periodic (at least quarterly) reports regarding GMS compliance matters related to this Appendix to the Board of Directors (or an authorized committee thereof) of GlaxoSmithKline PLC

(hereinafter, “the Board”), and shall be authorized to report on such matters to the Board at any time. The GMS Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The GMS Compliance Officer shall be responsible for oversight of the day-to-day compliance activities engaged in by GMS as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the GMS Compliance Officer shall be limited and must not interfere with the GMS Compliance Officer’s ability to perform the duties outlined in this CIA.

GSK shall report to OIG, in writing, any changes in the identity of the GMS Compliance Officer, or any actions or changes that would affect the GMS Compliance Officer’s ability to perform the duties necessary to meet the obligations in this Appendix, within 5 days after such a change.

2. *GMS Compliance Committee.* Prior to the Effective Date, GMS established a GMS Compliance Committee. The GMS Compliance Committee includes the GMS Compliance Officer and other members of GMS senior management necessary to meet the requirements of this Appendix. The GMS Compliance Officer shall co-chair the GMS Compliance Committee with the GMS President. The GMS Compliance Committee shall support the GMS Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the GMS’s cGMP risk areas and shall oversee monitoring of internal and external audits and investigations related to cGMP Requirements). The GMS Compliance Committee shall meet at least quarterly.

GSK shall report to OIG, in writing, any changes in the composition of the GMS Compliance Committee, or any actions or changes that would affect the GMS Compliance Committee’s ability to perform the duties necessary to meet the obligations in this Appendix, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* The Board shall be responsible for the oversight of matters related to compliance with cGMP Activities, applicable Federal health care program requirements, applicable FDA requirements, and the obligations of this Appendix.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee GMS’s Compliance Program, including but not limited to the performance of the GMS Compliance Officer and other GMS compliance personnel;
- b. for each Reporting Period of this Appendix, adopting a resolution, signed by each member of the Board summarizing its review and oversight of GMS’s compliance with cGMP Activities, applicable Federal health care program

requirements, applicable FDA requirements, and the obligations of this Appendix.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of the GMS Compliance Program for the time period [insert time period], including the performance of the GMS Compliance Officer. The Board has concluded that, to the best of its knowledge, GSK has implemented an effective Compliance Program, including a program that is effective to meet applicable Federal health care program requirements, applicable FDA requirements, and the obligations of this Appendix D to the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective GMS Compliance Program.

GSK shall report to the OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board’s ability to perform the duties necessary to meet the obligations in this Appendix, within 15 days after such change.

B. Written Standards

*Code of Conduct.* Prior to the Effective Date, GSK developed and adopted a written Code of Conduct (as described in Section III.B.1 of the CIA).

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall distribute the Code of Conduct to each Manufacturing Covered Person who is a GSK employee and each Manufacturing Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the Code of Conduct. New Manufacturing Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Manufacturing Covered Person or within 120 days after the Effective Date, whichever is later.

As provided in Section III.B of the CIA, GSK shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed to Manufacturing Covered Persons within 30 days to after any revisions are finalized. Each Manufacturing Covered Person shall certify, in writing or electronically, that he or she

has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

1. *Policies and Procedures.* Prior to the execution of the CIA, GSK implemented written Policies and Procedures regarding the operation of its GMS Compliance Program. Within 120 days after the Effective Date, GMS shall implement written procedures regarding any additional Compliance Program requirements outlined in this Appendix D. To the extent not already accomplished, within 120 days after the Effective Date, GMS shall ensure that the Policies and Procedures address or shall continue to address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1 of the CIA; and
- b. disciplinary policies and procedures for violations of the Company's Policies and Procedures, including policies relating to cGMP Activities and FDA requirements relating to cGMP Activities.

To the extent not already accomplished, within 120 days after the Effective Date, the Policies and Procedures shall be made available to all Manufacturing Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), GSK shall assess and update the Policies and Procedures, as necessary. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be made available to all Manufacturing Covered Persons.

#### C. Training and Education

GSK represents that it provides training on a regular basis concerning a variety of topics directly related to cGMP Activities. The training required by this Appendix need not be separate and distinct from the regular training provided by GSK to Manufacturing Covered Persons. At GSK's option, the training required by this Appendix may be integrated into the regular training provided by GSK.

1. *General Training.* Within 120 days after the Effective Date, GMS shall provide at least one hour of General Training to each Manufacturing Covered Person. This training, at a minimum, shall explain:

- a. The requirements of this Appendix D to the CIA; and

- b. GMS's Compliance Program, including the Company's Code of Conduct.

New Manufacturing Covered Persons shall receive the General Training described above within 30 days after becoming a Manufacturing Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Manufacturing Covered Person shall receive at least one hour of General Training during each subsequent Reporting Period.

*Board Member Training.* The training required by Section III.C.4 of the CIA shall include training on the obligations set forth in this Appendix.

2. *Certification.* Each individual who is required to receive training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training and the date upon which the training was completed. The GMS Compliance Officer (or designee) shall retain the certifications, along with all course materials.

3. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area, including about FDA requirements relating to cGMP Activities.

4. *Update of Training.* GMS shall review the content of each training program required by this Appendix annually and update the content of each training program, where appropriate, to reflect any material changes to cGMP requirements, changes to applicable Federal health care program requirements, FDA requirements, and any issues observed during internal audits.

5. *Computer-based Training.* GMS may provide the training required under this Appendix through appropriate computer-based training approaches. If GMS chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training. All applicable requirements to provide a number of "hours" of training as set forth in this Section III.C. may be met with respect to computer-based training by providing the required number of "normative" hours as that term is used in the computer-based training industry.

#### D. cGMP Requirements

1. In addition to existing FDA authorities and remedies, GSK agrees to certain obligations under this Appendix relating to cGMP Requirements for GSK drug products and vaccines. These provisions are in addition to other remedies available to the FDA.

2. If the Director of Compliance at FDA's Center for Drug Evaluation and Research (CDER), or in the case of a vaccine, the Director of Compliance at FDA's Center for Biologics Evaluation and Research (CBER) determines that a GSK facility (or facilities) manufacturing, processing, packing, or holding a GSK drug product or vaccine is not compliant with cGMP Requirements, FDA may so notify the OIG and recommend that OIG direct GSK to undertake a Specified Action as set forth below in section III.D.3 of this Appendix.

3. If, after reviewing FDA's notification and recommendation, OIG agrees that GSK should be directed to undertake a Specified Action as set forth in section III.D.3 of this Appendix, OIG shall notify GSK in writing of its determination and direct GSK to undertake one or more of the following actions (Specified Actions):

- a. Submit a report or information addressing the assertion of non-compliance to FDA and OIG within 10 days after the date of written notification from the OIG in accordance with the Notification provision in section III.D.4 below;
- b. In the event that OIG and/or FDA request additional or follow-up information, GSK shall submit revised, modified, or expanded report(s) or plan(s) to FDA and OIG in accordance with time frames established by the OIG and FDA; and/or
- c. Initiate a recall of the GSK drug product or vaccine in accordance with the instructions and time frames specified by OIG and FDA.

4. All notifications and reports required under this Section III.D shall be submitted to the following:

OIG

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201

FDA

Division of Manufacturing and Product Quality  
HFD-320  
Center for Drug Evaluation and Research  
10903 New Hampshire Avenue  
White Oak Bldg. 51  
Silver Spring, MD 20993

GSK

Guy Wingate  
Vice President - GMS Compliance Officer  
GlaxoSmithKline  
GSK House (Mailstop BNG-15)  
980 Great West Road  
Brentford  
Middlesex  
TW8 9GS  
United Kingdom

Paul Noll  
Vice President - Associate General Counsel  
Legal Operations - Global Manufacturing and Supply  
GlaxoSmithKline  
Five Moore Drive  
Ruvane Building - Mailstop E.3334  
Research Triangle Park, NC 27709

5. Within 10 days after receiving notification from the OIG of a Specified Action to be taken, GSK shall notify OIG and FDA in writing either:
- a. that GSK is undertaking or has undertaken the Specified Action, in which event GSK also shall describe the Specified Action taken or to be taken and the schedule for completing the action; or
  - b. that GSK does not agree with the OIG's determination that it failed to comply with cGMP Requirements and/or that the Specified Action is appropriate.

6. If GSK notifies OIG and FDA that it does not agree with the determination that it failed to comply with cGMP Requirements or that the Specified Action is appropriate:

- a. GSK shall explain in writing the basis for its disagreement; in so doing, GSK also may propose specific alternative actions and specific time frames to be substituted for the Specified Action required under this Section III.D.
- b. FDA shall review GSK's notification and thereafter, in writing, make a recommendation to OIG that OIG affirm, modify, or withdraw its proposed Specified Action.

7. Based on the advice of the FDA, OIG shall decide whether the determination that GSK failed to comply with cGMP Requirements and/or the proposed Specified Action shall be affirmed, modified, or withdrawn and shall provide written notice (Final Determination) to GSK of the Specified Action to be taken or of the withdrawal of the Specified Action. GSK shall, upon receipt of the notification of Final Determination, immediately implement the Final Determination.

8. GSK's failure to implement that Specified Action shall be the basis for Stipulated Penalties and or Material Breach Penalties under Section X of the CIA.

#### E. Manufacturing Reportable Events

1. *Definition of Manufacturing Reportable Event.* For purposes of this Appendix, a "Manufacturing Reportable Event" means conduct related to a Covered Manufacturing Facility or Covered Product that involves:

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to cGMP Activities; or
- b. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a of the CIA;

A Manufacturing Reportable Event may be the result of an isolated event or a series of occurrences. A Manufacturing Reportable Event does not include the following:

- a. Field Alert Reports submitted to FDA and related correspondence;

- b. Observations contained in FDA 483 Reports, GSK's responses to those observations and any related correspondence;
- c. Drug Quality Reporting System (DQRS) reports submitted to FDA and any related correspondence;
- d. Reports submitted to FDA relating to suspected or known counterfeit products and any related correspondence; and
- e. GSK Annual Product Reports for marketed products submitted to FDA and any related correspondence.

2. *Reporting of Manufacturing Reportable Events.* If GSK determines (after a reasonable opportunity to conduct an appropriate review or investigation) through any means that there is a Manufacturing Reportable Event, GSK shall, notify OIG in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Manufacturing Reportable Events under Section III.E.1.a-b.* For Manufacturing Reportable Events under Sections III.E.1.a-c, the report to OIG shall include:

- a. a complete description of the Manufacturing Reportable Event, including the relevant facts and persons involved and the legal authorities implicated;
- b. a description of GSK's actions taken to correct the Manufacturing Reportable Event; and
- c. any further steps GSK plans to take to address the Manufacturing Reportable Event and prevent it from recurring.

F. Reporting of Certain Events

If GSK voluntarily initiates a recall of a Covered Product manufactured at and/or released by either a Covered Manufacturing Facility or other GSK manufacturing facility located in the United States and that has been distributed in the United States, GSK shall notify OIG in writing within 5 days after initiating the recall.

**IV. CHANGES TO BUSINESS UNITS OR LOCATIONS**

Change of Status of a Covered Manufacturing Facility. In the event that, after the Effective Date, a new GSK facility located in the United States other than, or in

addition to, the Zebulon, North Carolina facility, manufacturers and/or releases for distribution in the United States Covered Products sold by GSK that are reimbursed by Federal health care programs, such facility may become a Covered Manufacturing Facility subject to the terms described below. As of the date that such new facility commences manufacture and/or release of a Covered Product, the Site Director, the Site Quality Director and all employees who are directly responsible for the release of Covered Products for distribution in the United States shall become Manufacturing Covered Persons. GSK shall have thirty (30) days to determine whether such new facility will continue to release Covered Products for distribution in the United States independently of the Zebulon, North Carolina facility. If, within the thirty (30) day period, GSK decides that such new facility will continue to release Covered Products independently of the Zebulon, North Carolina facility, then such facility shall become a Covered Manufacturing Facility and employees listed in Section II.C.1 of this Appendix shall be Manufacturing Covered Persons. If, within the thirty (30) day period, GSK determines that Covered Products manufactured at the new facility will be released under the supervision of the Zebulon, North Carolina facility, then such new facility shall not become a Covered Manufacturing Facility. In such event, the Site Director, the Site Quality Director and all employees at the facility who are directly responsible for authorizing the release of Covered Products for distribution in the United States shall be Manufacturing Covered Persons. GSK shall notify the OIG about the new Covered Manufacturing Facility in accordance with the timeframes specified in Section IV of the CIA.

## **V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Appendix Implementation Report. Within 150 days after the Effective Date, GSK shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Appendix (Appendix D Implementation Report). The Appendix D Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the GMS Compliance Officer required by Section III.A of this Appendix, and a summary of other noncompliance job responsibilities the GMS Compliance Officer may have;
2. the names and positions of the members of the GMS Compliance Committee required by Section III.A.2 of this Appendix;
3. the names of the members of the Board of Directors referenced in Section III.A.3 of this Appendix;
4. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1 of this Appendix, the percentage of individuals

who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG upon request);

5. a summary of all Policies and Procedures required by Section III.B of this Appendix (copies of the Policies and Procedures shall be made available to OIG upon request);

6. the following information regarding each type of training required by Section III.C of this Appendix:

- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be made available to OIG upon request.

7. A description of GSK's corporate structure as it relates to GMS and cGMP Activities; and

8. the certifications required by Section V.C of this Appendix.

B. Appendix Annual Reports. GSK shall submit to OIG annually a report with respect to the status of, and findings regarding, GMS's compliance activities for each of the five Reporting Periods (Appendix Annual Report).

Each Appendix Annual Report shall include, at a minimum:

1. Any change in the identity, position description, or other noncompliance job responsibilities of the GMS Compliance Officer, any changes in the membership of the GMS Compliance Committee, and any changes in the membership of the Board as described in Section III.A of this Appendix;

2. The Board resolution required by Section III.A.3 of this Appendix;

3. The number of individuals required to complete the Code of Conduct certification required by Section III.B.1 of this Appendix, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG upon request);

4. A summary of any significant changes or amendments to the Policies and Procedures required by Section III.B of this Appendix and the reasons for such changes.

5. The following information regarding each type of training required by Section III.C of this Appendix:

- a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

A copy of all training materials and the documentation to support this information shall be made available to OIG upon request.

6. A copy of any recall notices issued during the Reporting Period by GSK for Covered Products sold in the United States, a description of GSK's corrective action(s) taken related to the recall, and any further steps GSK plans to take related to the recall.

7. A summary of Manufacturing Reportable Events (as defined in Section III.E) identified during the Reporting Period and the status of any corrective action relating to each such Reportable Events;

8. A description of any changes to GSK's corporate structure as reported pursuant to Section V.A.7 of this Appendix D and an identification of any Covered Manufacturing Facility, if any, in lieu of or in addition to the Zebulon facility;

9. The certifications required by Section V.C.

The first Appendix Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Appendix Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Appendix Annual Report.

C. Certifications. The Appendix Implementation Report and each Appendix Annual Report shall include a certification by the GMS Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the report, GMS is in compliance in all material respects with cGMP Requirements and all of the requirements of this CIA; and

2. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful.

D. Designation of Information. GSK shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. GSK shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this Appendix D shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

GSK:

Guy Wingate  
Vice President - GMS Compliance Officer  
GlaxoSmithKline  
GSK House (Mailstop BNG-15)  
980 Great West Road  
Brentford  
Middlesex  
TW8 9GS  
United Kingdom  
Telephone: +44-1833-693330  
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Paul Noll  
Vice President - Associate General Counsel  
Legal Operations - Global Manufacturing and Supply  
GlaxoSmithKline  
Five Moore Drive  
Ruvane Building - Mailstop E.3334  
Research Triangle Park, NC 27709  
Telephone: (919) 483-2444  
Facsimile: (919) 483-2881

Unless otherwise specified, all notifications and reports required by this Appendix may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, GSK may be required to provide OIG with an electronic copy of each notification or report required by this Appendix to the CIA in searchable portable document format (pdf), in addition to a paper copy.

## Appendix E to CIA for GlaxoSmithKline LLC

### Executive Financial Recoupment Program

**Executive Financial Recoupment Program.** Through its Existing Commitments and the New Commitments to be implemented, GSK shall establish and maintain throughout the term of the CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay (*i.e.*, annual bonus, plus long term incentives) for an executive who is discovered to have been involved in any significant misconduct (Executive Financial Recoupment Program). This financial recoupment program shall apply to Covered Executives, as defined below in Paragraph B, who are either current GSK employees or who are former GSK employees at the time of a Recoupment Determination.

(A) **Existing Commitments.** The annual cash bonus for each GSK employee based in the United States and the United Kingdom is at risk of forfeiture in the event of employee misconduct that is discovered by GSK before the bonus is paid. In the event of misconduct by any GSK employee worldwide, GSK also has reserved the right and full discretion to void and forfeit any unvested share options and any unvested restricted share grants under the GSK Share Option Plan, Share Value Plan and Performance Share Plan (collectively, the “LTI Plans”). If GSK discovers any employee misconduct that would implicate the forfeitures described in this paragraph, it shall evaluate the situation and make a determination about whether any forfeiture, and the terms of such forfeiture, shall be implemented.

(B) **New Commitments.** In addition to the compensation forfeiture provisions already in place with respect to annual bonuses and the LTI Plans, within 120 days after the Effective Date of the CIA, GSK shall modify and supplement its annual bonus plan and LTI Plan requirements (and any employment agreements, as appropriate) by imposing the following eligibility and repayment conditions on future bonuses and LTI Plan grants, as well as establishing the mandatory deferred annual bonus, tolling remedy, and additional remedies discussed below (collectively, “New Commitments”) to all members of GSK’s Corporate Executive Team (CET) and to any Vice Presidents and Senior Vice Presidents in Grades 0, 1, and 2 who are based in the United States (collectively “Covered Executives”). The New Commitments shall apply prospectively to Covered Executives beginning with the 2013 bonus plan year and LTI Plan grants.

(i) **Executive Bonus Eligibility and Repayment Conditions.** GSK shall implement an eligibility and repayment condition on annual bonuses designed to survive both the payment of the bonus and the separation of a Covered Executive’s employment. This will allow GSK, as a consequence of a Triggering Event as defined below in Paragraph C, to pursue repayment from the Covered Executive of all or any portion of the bonus monies paid to the Covered Executive. To the extent permitted by

controlling law, these bonus eligibility and repayment conditions will survive the payment of the Covered Executive's bonus and the separation of the Covered Executive's employment for a period of 3 years from the payment of the bonus for the plan year.

Consistent with a Recoupment Determination, as defined below in Paragraph D, GSK shall endeavor to collect repayment of any bonus from the Covered Executive through reasonable and appropriate means according to the terms of its bonus plan (or executive contract, as the case may be), and to the extent permitted by controlling law of the relevant jurisdiction. If necessary to collect the repayment, GSK shall file suit against the Covered Executive unless good cause exists not to do so. For purposes of the Executive Financial Recoupment Program, good cause shall include, but not be limited to, a financial inability on the part of the Covered Executive to repay any recoupment amount or GSK's inability to bring such a suit under the controlling law of the relevant jurisdiction.

(ii) **LTI Plans.** Prior to the Effective Date, GSK implemented a recoupment process for Covered Executives' unvested LTI share grants as discussed in Paragraph A (Existing Commitments) above. With respect to current GSK Covered Executives, GSK shall maintain these Existing Commitments and follow the Recoupment process and procedures established by the Recoupment Committee for the duration of the CIA. GSK shall also implement an eligibility and repayment condition on share grants made under LTI Plans designed to survive the separation of a Covered Executive's employment.

To the extent necessary, GSK shall implement an eligibility and repayment condition on grants made under the LTI Plans in order to clarify that, as a consequence of a Triggering Event, GSK may pursue repayment by a Covered Executive who is a former employee of all or any portion of the last 3 years' worth of share option and restricted share grants that became vested and were paid during the Covered Executive's last years of employment and following termination of employment.

To the extent permitted by controlling law, these eligibility and repayment conditions shall survive vesting and payment for a period of 3 years from the Covered Executive's employment termination date. In addition, GSK shall amend the vesting schedule in the LTI Plans so that Covered Executives who are "good leavers" (e.g., terminating employment due to retirement, death or disability) will no longer vest in, nor receive a distribution of, any unvested share options or restricted shares immediately following termination of employment; rather, these LTI Plan grants will only vest and be distributable after the first anniversary of the Covered Executive's termination of employment. Consistent with a Recoupment Determination, GSK shall endeavor to collect repayment of these LTI Plan awards from the Covered Executive through reasonable and appropriate means and to the extent permitted by controlling law of the jurisdiction in which the Covered Executive works. If necessary to collect the

repayment, GSK shall file suit against the Covered Executive unless good cause exists not to do so.

(iii) **Mandatory Deferred Annual Bonus.** GSK shall establish a deferred compensation plan that requires the deferral of ten (10%) percent of a Covered Executive's annual bonus (twenty-five (25%) percent, in the case of CET members) for a 3-year period that survives separation of the Covered Executive's employment. Bonuses deferred under the plan shall be matched on a dollar-for-dollar basis by GSK. Consistent with a Recoupment Determination, all deferred bonuses, matching contributions and any related gains thereon are subject to forfeiture and voidance as a consequence of a Triggering Event.

(iv) **Tolling Remedy.** To the extent permitting by controlling law, for the 3 years during which the bonus eligibility and repayment conditions exist, if GSK reasonably anticipates that a Triggering Event has occurred pursuant to Paragraph C, and GSK has recoupment rights remaining under Paragraphs B(i) and B(ii), GSK shall have the right to notify the Covered Executive that those rights shall be tolled and thereby extended for an additional 3 years or until the Recoupment Committee determines that a Triggering Event has not occurred, whichever is earlier, to the extent permitted by controlling law of the relevant jurisdiction.

(v) **Additional Remedies.** If, after expiration of the time period specified in Paragraphs B(i)-(iii) above, the Recoupment Committee determines that a Triggering Event occurred, GSK shall make a determination as to whether to pursue available remedies (*e.g.*, filing suit against the Covered Executive) existing under statute or common law to the extent available.

(C) **Definition of Triggering Events.** The eligibility and repayment conditions described above shall be triggered upon a Recoupment Determination that finds:

(i) significant misconduct (*e.g.*, violation of a significant GSK policy, or regulation, or law) by the Covered Executive that, if discovered prior to payment, would have made the Covered Executive ineligible for an annual bonus, bonus deferral or LTI Plan grant in that plan year or subsequent plan years; or

(ii) significant misconduct by subordinate employees in the business unit over which the Covered Executive had responsibility that does not constitute an isolated occurrence and which the Covered Executive knew or should have known was occurring that, if discovered prior to payment, would have made the Covered Executive and/or employees in question ineligible for an annual bonus, bonus deferral or LTI Plan grant in that plan year or subsequent plan years.

(D) **Administration of Recoupment Program.** GSK shall engage in a standardized, formal process to determine, in its sole discretion, whether a Triggering Event has occurred, and, if so, the extent of bonus monies, LTI Plan grants and deferred compensation that will be subject to repayment or forfeiture by the Covered Executive, and the most appropriate method for securing recoupment of relevant monies previously paid to a Covered Executive. The findings and conclusions resulting from this process shall be referred to as the “Recoupment Determination”.

(i) **Initiation.** GSK shall initiate the Recoupment Determination process upon: (1) discovery of potential significant misconduct that may rise to the level of a Triggering Event, or (2) written notification by a United States federal government agency to the Senior Vice President for Governance, Ethics, and Assurance of GlaxoSmithKline PLC of a situation that may rise to the level of a Triggering Event and either occurred in the United States or gives rise to liability relating to Federal healthcare programs. This written notification shall either identify the Covered Executive(s) potentially at issue or provide information (*e.g.*, a description of the alleged misconduct and the applicable time period) to allow GSK to identify the Covered Executive.

(ii) **Recoupment Committee.** The Recoupment Determination shall be made by a committee of senior executives headed by the Senior Vice President for Governance, Ethics, and Assurance of GlaxoSmithKline PLC (Recoupment Committee). With respect to members of the CET, a Recoupment Determination shall be subject to ratification by the Board of Directors (or appropriate committee thereof) of GlaxoSmithKline PLC.

(iii) **Timeline for Recoupment Determination Process.** GSK shall initiate the Recoupment Determination process within 30 days after discovery by GSK or notification, pursuant to Paragraph D(i), of a potential Triggering Event. Absent extraordinary reasons, GSK shall reach a Recoupment Determination within 90 days after initiation of the determination process.

In connection with making its Recoupment Determination, the Recoupment Committee or appropriate Delegate pursuant to implementing policies and procedures shall: i) undertake an appropriate and substantive review or investigation of the facts and circumstances associated with the Triggering Event or any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; ii) make written findings regarding the facts and circumstances associated with the Triggering Event and any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; and iii) set forth in writing its determinations (and the rationale for such determinations) about: 1) whether a Triggering Event occurred; 2) the extent of

bonus monies, LTI Plan grants or deferred compensation that will be subject to forfeiture and/or repayment by the Covered Executive; 3) the means that will be followed to implement the forfeiture and/or secure the recoupment of performance pay from the Covered Executive; and 4) the timetables under which GSK will implement the forfeiture and/or attempt to recoup the performance pay. For purposes of this paragraph, a “Delegate” shall refer to the GSK personnel to whom the Recoupment Committee has delegated one or more of its required tasks in furtherance of the Executive Financial Recoupment Program.

(E) **Reporting.** The Recoupment Committee shall provide annual reports to the Board of Directors (or an appropriate committee thereof) of GlaxoSmithKline PLC about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; ii) a description of any Recoupment Determinations made during the preceding year (including any decision to require or not require forfeiture/recoupment from any Covered Executives, the amount and type of any forfeiture/recoupment, the means for collecting any recoupment and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Recoupment Determinations that were not fully completed in prior years.

The Recoupment Committee shall also provide annual reports to the OIG about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; ii) a summary description of any Recoupment Determinations made during the preceding year (including any decision to require or not require forfeiture/recoupment from any Covered Executives, the amount and type of any forfeiture/recoupment, the method for collecting any recoupment, and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Recoupment Determinations that were not fully completed in prior years.

GSK commits to maintaining all of the forfeiture and recoupment commitments set forth in Paragraphs A-E above for at least the duration of the CIA, absent agreement otherwise with the OIG.



# GSK China Investigation Outcome

## 19 September 2014

GlaxoSmithKline plc (GSK) today announced that the Changsha Intermediate People's Court in Hunan Province, China ruled that GSK China Investment Co. Ltd (GSKCI) has, according to Chinese law, offered money or property to non-government personnel in order to obtain improper commercial gains, and been found guilty of bribing non-government personnel. The verdict follows investigations initiated by China's Ministry of Public Security in June 2013.

As a result of the Court's verdict, GSKCI will pay a fine of £297 million (3 billion RMB at a currency exchange rate of 10.0980) to the Chinese government. This will be funded through existing cash resources. Associated costs and charges related to restructuring will be included in GSK's third quarter update.

The illegal activities of GSKCI are a clear breach of GSK's governance and compliance procedures; and are wholly contrary to the values and standards expected from GSK employees. GSK has published a statement of apology to the Chinese government and its people on its website ([www.gsk-china.com](http://www.gsk-china.com)).

GSK has co-operated fully with the authorities and has taken steps to comprehensively rectify the issues identified at the operations of GSKCI. This includes fundamentally changing the incentive program for its salesforces (decoupling sales targets from compensation); significantly reducing and changing engagement activities with healthcare professionals; and expanding processes for review and monitoring of invoicing and payments.

GSK Chief Executive Officer, Sir Andrew Witty said: "Reaching a conclusion in the investigation of our Chinese business is important, but this has been a deeply disappointing matter for GSK. We have and will continue to learn from this. GSK has been in China for close to a hundred years and we remain fully committed to the country and its people. We will continue to expand access to innovative medicines and vaccines to improve their health and well-being. We will also continue to invest directly in the country to support the government's health care reform agenda and long-term plans for economic growth."

Exhibit

6

GSK – one of the world’s leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit [www.gsk.com](http://www.gsk.com).

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**ADMINISTRATIVE PROCEEDING**  
**File No. 3-17606**

**GlaxoSmithKline Pays \$20 Million Penalty to Settle FCPA Violations**

**September 30, 2016** – The Securities and Exchange Commission today announced that GlaxoSmithKline plc (“GSK”) has agreed to pay \$20 million to settle charges that it violated the Foreign Corrupt Practices Act (FCPA) when its China-based subsidiaries engaged in pay-to-prescribe schemes to increase sales.

An SEC investigation found that the schemes spanned a period of years and involved the transfer of money, gifts, and other things of value to health care professionals, which led to millions of dollars in increased sales of GSK pharmaceutical products to China’s state health institutions. The participants included certain complicit sales and marketing managers within GSK’s China-based subsidiaries. GSK failed to devise and maintain a sufficient system of internal accounting controls and lacked an effective anti-corruption compliance program to detect and prevent these schemes. As a result, the improper payments were not accurately reflected in GSK’s books and records.

The SEC’s order finds that GSK violated the FCPA’s internal controls and books-and-records provisions. GSK consented to the order without admitting or denying the findings, and agreed to pay a \$20 million civil penalty. GSK also agreed to provide status reports to the SEC for the next two years on its remediation and implementation of anti-corruption compliance measures.

**See also:**     [Order](#)

# # #

**UNITED STATES OF AMERICA**  
**Before the**  
**SECURITIES AND EXCHANGE COMMISSION**

**SECURITIES EXCHANGE ACT OF 1934**  
**Release No. 79005 / September 30, 2016**

**ACCOUNTING AND AUDITING ENFORCEMENT**  
**Release No. 3810 / September 30, 2016**

**ADMINISTRATIVE PROCEEDING**  
**File No. 3-17606**

**In the Matter of**

**GlaxoSmithKline plc,**

**Respondent.**

**ORDER INSTITUTING CEASE-AND-DESIST  
PROCEEDINGS, PURSUANT TO SECTION  
21C OF THE SECURITIES EXCHANGE ACT  
OF 1934, MAKING FINDINGS, AND  
IMPOSING REMEDIAL SANCTIONS AND A  
CEASE-AND-DESIST ORDER**

**I.**

The Securities and Exchange Commission (“Commission”) deems it appropriate that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 21C of the Securities Exchange Act of 1934 (“Exchange Act”), against GlaxoSmithKline plc (“Respondent”).

**II.**

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the “Offer”) which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission’s jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings, Pursuant to 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing Remedial Sanctions and a Cease-and-Desist Order (“Order”), as set forth below.

### III.

On the basis of this Order and Respondent's Offer, the Commission finds<sup>1</sup> that

#### **Summary**

A. These proceedings arise out of GSK's violations of the internal controls and recordkeeping provisions of the Foreign Corrupt Practices Act of 1977 (the "FCPA") [15 U.S.C. § 78dd].

B. Between at least 2010 and June 2013, employees and agents of GSK's China-based subsidiary and a China-based joint-venture engaged in various transactions and schemes to provide things of value to foreign officials, including healthcare professionals ("HCPs"), in order to improperly influence them and increase sales of GSK products in China.

C. This misconduct was facilitated in part by the use of collusive third parties that ostensibly provided legitimate travel and other services. The funds used for the improper inducements were frequently obtained under the guise of, and falsely recorded in GSK's books and records as, legitimate travel and entertainment expense, marketing expense, speaker payments, medical associations payments, and promotion expense. Throughout this period GSK failed to devise and maintain a sufficient system of internal accounting controls and lacked an effective anti-corruption compliance program.

D. The deficiencies in GSK's internal accounting controls and compliance program also led to instances of similar improper conduct in connection with sales in other countries in which GSK operates.

#### **Respondent**

E. GlaxoSmithKline plc is a corporation organized in the United Kingdom. Its headquarters are located in Middlesex, United Kingdom. GSK's common stock is registered with the Commission under Section 12(b) of the Securities Exchange Act and trades on the New York Stock Exchange under the symbol 'GSK'.

F. GSK is a global provider of pharmaceutical and consumer health care products and its products are sold in at least 150 countries.

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<sup>1</sup> The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

### **Other Relevant Entities**

G. **GlaxoSmithKline (China) Investment Co Ltd** (“GSKCI”) is operated from Shanghai, China. GSKCI operations include the sale and marketing of pharmaceutical products. GSKCI is a wholly-owned indirect subsidiary of GSK.

H. **Sino-American Tianjin Smith Kline & French Laboratories Ltd** (“TSKF”) is a public-private joint venture with Tianjin Zhong Xin Pharmaceutical Group Corporation Ltd and Tianjin Pharmaceutical Group Co Ltd. GSK indirectly owns 55 percent of TSKF.

### **Facts**

I. From at least 2010 to June 2013, employees and agents of GSKCI and TSKF engaged in transactions and schemes to corruptly transfer things of value to foreign officials in China to increase sales of pharmaceutical products. The payments were made to increase sales through increased prescriptions by individual HCPs and purchases by hospital administrative staff responsible for product selection or purchase. The conduct occurred across all geographic areas within the sales and marketing functions and impacted all product lines.

J. The corrupt payments took varied forms, including gifts, improper travel and entertainment with no or little educational purpose, shopping excursions, family and home visits, and cash. The costs associated with these payments were recorded in GSK’s books and records as legitimate expenses, such as medical association sponsorships, employee expenses, conferences, speaker fees, and marketing costs.

K. These improper practices were pervasive among GSKCI’s and TSKF’s sales and marketing representatives and were condoned by regional and district managers. For example, a 2013 work plan submitted by a sales representative to a regional sales manager described the intent to pay, among other things, an HCP RMB 20/box of prescribed product every month, and deliver appropriate gifts on each holiday in exchange for a guarantee of more than 40 boxes of prescribed product every month.

L. Among the ways employees were able to fund payments to HCPs was the use of collusive third party vendors, such as those used to perform planning and travel services for events involving HCPs. Between 2010 and June 2013, GSKCI spent nearly RMB 1.4 billion (USD \$225 million) on planning and travel services. Test sampling showed that approximately 44 percent of the sampled invoices were inflated and approximately 12 percent were for events that did not occur.

M. Controls weaknesses also permitted ostensibly legitimate speaker fees to be used to improperly influence HCPs. While GSK’s policies as of 2010 placed limits on the amount of fees paid to speakers per hour and by 2012 cumulatively per year, there was no effective system in place to ensure the actual identity of a speaker. Of approximately RMB 106 million (USD \$17 million) spent by GSKI in speaker fees, approximately RMB 14 million (USD \$2.2 million) was paid to persons whose qualification as an HCP could not be verified.

N. Marketing programs were another mechanism used to improperly influence HCPs. For example, in 2010, GSKCI engaged a local vendor to facilitate a national marketing program called the Cold Chain Project. The project was intended to provide healthcare clinics with tools to facilitate the storage and administration of vaccines that required refrigeration. However, the project was instead used to provide HCPs with gifts such as laptops, tablets, and other electronic devices. Over the life of the project, GSKCI paid out RMB 14.6 million (approximately USD \$2.3 million). The project was created and administered by senior marketing and sales managers of GSKCI. The clinics selected were based upon the potential to market additional pharmaceutical products.

O. During this period, local internal audit and compliance reviews identified controls deficiencies and evidence of some mechanisms that were used to fund the improper payments, but they were treated as isolated instances rather than signs of a larger problem. For example, in 2013 a Sales Rep Office Audit was conducted by internal audit with respect to the Guangzhou office. Among the problems identified were:

- Issues of falsified POS slips and fake bank statements
- Issues of fake invoices claimed from hotels and restaurants for sales meeting activities. These invoices came from a local preferred meeting agency used by the Guangzhou office.
- Compliance and New Employee training not timely completed
- Sales employees' salaries were significantly driven by commissions that could lead to an incentive to improperly inflate sales. The audit sampled 20 percent of the sales team for the office and found that for 41 percent their sales commission bonuses were greater than 50 percent of their income.

P. As early as 2010, internal audit identified problems related to sales and promotions staff practices in China. Among other findings it noted:

[d]uring 2010, several new policies governing commercial activities such as grants and donations and sponsorships were introduced. The significant changes, combined with the high staff turnover, contribute to an environment where many commercial and medical staff do not understand how to apply policies or the rationale behind them. This was evidenced by approval of non-compliant activities, a lack of clarity on which policy to apply for activities such as grants, and weaknesses in documentation to support the legitimate intent of activities such as advisory boards and sponsorships of HCPs to attend meetings.

Q. As a result of the conduct described above, Respondent violated Sections 13(b)(2)(A) and 13(b)(2)(B) of the Securities Exchange Act of 1934 [15 U.S.C. §§ 78m(b)(2)(A) and 78m(b)(2)(B)].

### **GSK's Remedial Efforts**

R. In determining to accept the Offer, the Commission considered remedial acts promptly undertaken by Respondent and cooperation afforded the Commission staff.

1. During the course of the investigation, Respondent provided prompt and regular briefings regarding its own internal investigation in China, and with respect to other countries. Respondent timely conveyed the facts it learned in the course of its own investigation, promptly responded to document requests by the Commission staff, and provided translations of documents as needed.
2. Respondent also provided detailed and timely information regarding its remedial efforts, enhancements to its compliance program and implementation of key initiatives.
3. Respondent made global changes to its business. This included the elimination of most payments to doctors, including fees to HCPs to speak about the Company's prescription medicines, and altering the compensation structure for its sales force to eliminate incentive pay based on the number of prescriptions generated. Respondent enhanced its global risk assessment process, strengthened its monitoring and risk assessment tools, and increased its global compliance organization. Respondent also enhanced its third-party oversight program, including increasing the number and scope of third-party audits, and increased training and education of employees on anti-bribery issues.

### **Undertakings**

S. Respondent has undertaken to:

1. Report to the Commission staff periodically, at no less than nine-month intervals during a two-year term, the status of its remediation and implementation of compliance measures. During this two-year period, should Respondent discover credible evidence, not already reported to the Commission staff, that questionable or corrupt payments or questionable or corrupt transfers of value may have been offered, promised, paid, or authorized by Respondent, or any entity or person acting on behalf of Respondent, or that related false books and records have been maintained, Respondent shall promptly report such conduct to the Commission staff. During this two-year period, Respondent shall: (a) conduct an initial review and submit an initial report, and (b) conduct and prepare at least two follow-up reviews and reports, as described below:
  - i. Respondent shall submit to the Commission staff a written report within 180 calendar days of the entry of this Order setting forth a complete description of its Foreign Corrupt Practices Act ("FCPA") and anti-corruption related remediation efforts to

date, its proposals reasonably designed to improve the policies and procedures of Respondent for ensuring compliance with the FCPA and other applicable anticorruption laws, and the parameters of the subsequent reviews (the “Initial Report”). The Initial Report shall be transmitted to Charles Cain, Deputy Unit Chief, FCPA Unit, Division of Enforcement, United States Securities and Exchange Commission, 100 F St NE, Washington, DC 20549. Respondent may extend the time period for issuance of the Initial Report with prior written approval of the Commission staff.

- ii. Respondent shall undertake at least two follow-up reviews, incorporating any comments provided by the Commission staff on the previous report, to further monitor and assess whether the policies and procedures of Respondent are reasonably designed to detect and prevent violations of the FCPA and other applicable anti-corruption laws (the “Follow-up Reports”).
  - iii. The first Follow-up Report shall be completed by no later than 270 days after the Initial Report. The second Follow-up Report shall be completed by no later than 450 days after the completion of the Initial Report. Respondent may extend the time period for issuance of the Follow-up Reports with prior written approval of the Commission staff.
  - iv. The periodic reviews and reports submitted by Respondent will likely include proprietary, financial, confidential, and competitive business information. Public disclosure of the reports could discourage cooperation, impede pending or potential government investigations and thus undermine the objectives of the reporting requirement. For these reasons, among others, the reports and the contents thereof are intended to remain and shall remain non-public, except (a) pursuant to court order, (b) as agreed by the parties in writing, (c) to the extent that the Commission staff determines in its sole discretion that disclosure would be in furtherance of the Commission’s discharge of its duties and responsibilities, or (d) is otherwise required by law.
2. Certify, in writing, compliance with the undertaking(s) set forth above. The certification shall identify the undertaking(s), provide written evidence of compliance in the form of a narrative, and be supported by exhibits sufficient to demonstrate compliance. The Commission staff may make reasonable requests for further evidence of compliance, and Respondent agrees to provide such

evidence. The certification and supporting materials shall be submitted to Charles Cain, Deputy Unit Chief, FCPA Unit, with a copy to the Office of the Chief Counsel of the Enforcement Division, no later than sixty (60) days from the date of the completion of the undertakings.

#### IV.

In view of the foregoing, the Commission deems it appropriate to impose the sanctions agreed to in Respondent's Offer. Accordingly, pursuant to Section 21C of the Exchange Act, it is hereby ORDERED that:

A. Respondent cease and desist from committing or causing any violations and any future violations of Sections 13(b)(2)(A) and 13(b)(2)(B) of the Securities Exchange Act of 1934 [15 U.S.C. §§ 78m(b)(2)(A) and 78m(b)(2)(B)].

B. Respondent shall, within 10 days of the entry of this Order, pay a civil money penalty in the amount of \$20,000,000 to the Securities and Exchange Commission for transfer to the general fund of the United States Treasury, subject to Exchange Act Section 21F(g)(3). If timely payment is not made, additional interest shall accrue pursuant to 31 U.S.C. §3717. Payment must be made in one of the following ways:

- (1) Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;
- (2) Respondent may make direct payment from a bank account via Pay.gov through the SEC website at <http://www.sec.gov/about/offices/ofm.htm>; or
- (3) Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center  
Accounts Receivable Branch  
HQ Bldg., Room 181, AMZ-341  
6500 South MacArthur Boulevard  
Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying GSK as a Respondent in these proceedings, and the file number of these proceedings; a copy of the cover letter and check or money order must be sent to Charles Cain, Division of Enforcement, Securities and Exchange Commission, 100 F St., NE, Mailstop 5631, Washington, DC 20549.

C. Amounts ordered to be paid as civil money penalties pursuant to this Order shall be treated as penalties paid to the government for all purposes, including all tax purposes. To preserve the deterrent effect of the civil penalty, Respondent agrees that in any Related Investor

Action, it shall not argue that it is entitled to, nor shall it benefit by, offset or reduction of any award of compensatory damages by the amount of any part of Respondent's payment of a civil penalty in this action ("Penalty Offset"). If the court in any Related Investor Action grants such a Penalty Offset, Respondent agrees that it shall, within 30 days after entry of a final order granting the Penalty Offset, notify the Commission's counsel in this action and pay the amount of the Penalty Offset to the Securities and Exchange Commission. Such a payment shall not be deemed an additional civil penalty and shall not be deemed to change the amount of the civil penalty imposed in this proceeding. For purposes of this paragraph, a "Related Investor Action" means a private damages action brought against Respondent by or on behalf of one or more investors based on substantially the same facts as alleged in the Order instituted by the Commission in this proceeding.

D. Respondent shall comply with the undertakings enumerated in Section III above.

By the Commission.

Brent J. Fields  
Secretary

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PETER HUMPHREY,  
YU YINGZENG  
CHINAWHYS COMPANY LTD

Plaintiffs,

V,

GLAXOSMITHKLINE PLC;  
GLAXOSMITHKLINE LLC

Defendants.

Case No. 2:16 cv 5924

**DECLARATION OF GSK CHINA (INVESTMENT) CO. LTD.**

I, Thomas Willemsen, being above 18 years of age and competent to make this declaration, hereby declare that:

1. My name is Thomas Willemsen. I am aware and cognizant of the facts set forth in this Declaration and am able to swear, and I hereby do swear, that all of the matters contained in this Declaration are true and correct.

2. I am currently employed as VP and General Manager, China Pharmaceuticals and Vaccines, for GlaxoSmithKline (China) Investment Co. Ltd. ("GSK China").

3. GSK China is a wholly-owned indirect subsidiary of GlaxoSmithKline plc ("GSK PLC"), and it is incorporated under Chinese law.

4. GSK China and GSK PLC maintain all the formalities of separate corporations. GSK China maintains books and records, payrolls, bank accounts, and a board of directors

independently of GSK PLC. GSK China and GSK PLC are separately and adequately capitalized.

5. GSK China's principal place of business is in Shanghai, China.

6. GSK China has never conducted commercial operations in the United States or the Commonwealth of Pennsylvania.

7. GSK China was the GSK entity which executed the Consultancy Agreement entered into between GSK China and ChinaWhys, through the ChinaWhys alter egos ChinaWhys (Shanghai) Consulting Co. Ltd. and ChinaWhys Co. Ltd., which is the subject of the within litigation. No other GSK entity was a party to the Consultancy Agreement.

8. From April through July of 2013, the below-referenced GSK-affiliated individuals named in the above referenced complaint ("Complaint") were employed by GSK China, based in China, and performed services that were directed towards China:

- a. Mark Reilly;
- b. April Zhao;
- c. Leslie Chang; and
- d. Maggie Zheng.

9. From April through July of 2013, Jennifer Huang was employed by GlaxoSmithKline (China) R&D Company Limited, based in China, and performed services that were directed towards China.

10. From April through July 2013, Brian Cahill ("Cahill") was an employee of GlaxoSmithKline Pte. Ltd., was based in Singapore, and was employed as Senior Vice President and General Counsel, Asia. During April through July 2013, Cahill had oversight over GSK China's legal operations, among other responsibilities.

11. From April through July 2013, June Soon was an employee of GlaxoSmithKline

Pte. Ltd., was based in Singapore, and was employed as an executive secretary supporting Cahill.

12. On July 2, 2012, GSK LLC agreed to plead guilty and to pay \$3 billion to resolve criminal and civil liabilities arising from the promotion of certain prescription drugs, the failure to report certain safety data, and its civil liabilities for alleged false price reporting practices, arising from various conduct that occurred in the United States between 1994 - 2010 ("2012 U.S. Settlement"). GSK China was not a party to the 2012 U.S. Settlement.

13. On September 19, 2014, the Changsha Intermediate People's Court in Hunan Province, China entered a judgment against GSK China for approximately \$489.5 million in connection with violations by GSK China personnel of Chinese law prohibiting bribery of non-governmental Chinese personnel ("2014 China Judgment"). None of the conduct that was the subject of the 2014 China Judgment occurred in the United States. Neither GSK PLC nor GSK LLC were parties to the 2014 China Judgment.

14. On September 30, 2016, the United States Securities and Exchange Commission ("U.S. SEC") and GSK PLC entered into a civil resolution concerning internal controls and recordkeeping provisions of the United States Foreign Corrupt Practices Act of 1977 relating to conduct in China involving GSK China and a related joint-venture ("2016 U.S. Settlement"). GSK China was not a party to the 2016 U.S. Settlement.

\* \* \*

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

DATE:

Jan 16, 2017



Thomas Willemssen



# ChinaWhys

|| About Us ||

## An International Business Risk Advisory Firm with Eyes in China

As the global supply chain undergoes a quantum shift, with multinational corporations relocating their supply base to Asia and increasingly to China, with global sourcing operations centering on this region, the risks and challenges can sometimes be as great as and sometimes greater than the rewards and profits. ChinaWhys is there to help you avoid the landmines.

Outsourcing, localization and technology transfer are irresistible trends that go hand in hand with the supply chain shift, bringing efficiencies, economies, competitiveness, enhanced profitability, but also the new and hidden dangers of an unknown landscape.

We are international business advisors with eyes in China, walking multinationals through the labyrinth of opportunity, risk and unfamiliar cultural environment.

ChinaWhys is a professional-services consultancy that specializes in discreet risk mitigation solutions, consulting and investigation services to corporate clients in matters of high sensitivity across Greater China and the Asia Pacific. Incorporated in Hong Kong, ChinaWhys has an extensive and discreet network of resources across China and the region, and has associates in all regions of the world.

ChinaWhys was founded in 2003 by Peter Humphrey, who has spent more than 30 years dealing with China and Eastern Europe. He has set the standard for the risk mitigation industry in China through his service to multinationals during China's recent opening-up to world business.

We have provided regular advice to the business community on risk management and conducted services in China for large, medium and small multinationals, professional services firms, NGOs, chambers of commerce and high wealth individuals.

We are a cost-effective practice with an extensive network of contacts with regulatory agencies, investigators, international and local law firms, and professionals across the country that enables us to conduct wide ranging discreet inquiries into difficult commercial matters ranging from pre-transactional issues, and fraud and employee corruption, to intellectual property abuse and other business crises. We have experience in serving a wide spectrum of industries from manufacturing and logistics to law practices and accounting firms.

[Click here to understand the Reality of Business Risk and our Objectives.](#)



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# ChinaWhys

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## Peter Humphrey

### Managing Director of ChinaWhys

Peter is the founder of ChinaWhys, a risk management consultancy that provides creative approaches to critical business problems in China. ChinaWhys offers discreet risk mitigation solutions, consulting and commercial investigation services to corporate clients in important and sensitive matters across the Greater China region and beyond.

Peter has spent 37 years involved with China and Eastern European countries. After two decades as a foreign correspondent with Reuters in Asia, Eastern Europe and the Balkans, he has spent the past 14 years as a risk management specialist and corporate detective focused on white-collar crime prevention, fraud investigation and crisis mitigation for multinationals in Asia.

Before founding ChinaWhys, Peter had served as China country manager for US risk consultancy Kroll and head of China investigations at PwC as well as undertaking a number of humanitarian assignments.

Peter has a thorough knowledge of the China operating environment and is an authority on fraud and supply chain risks. He resolves critical problems for Fortune 500 companies and works closely with leading international law firms. His successes include neutralizing a counterfeit-and-fraud syndicate that hijacked the business of a global consumer goods manufacturer, eliminating fraud from the buying operation of a leading megastore chain, uncovering fraudulent JV deals for a global appliances manufacturer, and orchestrating the recovery of a kidnapped child in China.

He holds an Honours degree in Oriental Studies from Durham University England and was a fellow of Harvard University 1994-1996. He is fluent in spoken Mandarin and reads and writes Chinese and other foreign languages. He is Founding President of the Shanghai Chapter of the Association of Certified Fraud Examiners (ACFE) and a member of the American Society for Industrial Security (ASIS). He is also active in community service and charity work for underprivileged communities, and served as President of the Rotary Club of Beijing in 2010-2011.

ChinaWhys  
PEOPLE

Peter  
Humphrey

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Exhibit

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# ChinaWhys

|| About Us ||

## Yingzeng Yu

### General Manager of ChinaWhys

Yingzeng, ("Ying") is a founder and director of ChinaWhys, a risk management and supply chain services consultancy that provides creative approaches to critical business problems in China. ChinaWhys offers discreet risk mitigation solutions, internal process audits, due diligence and commercial investigation services to corporate clients in matters of great importance and sensitivity across the Greater China region and beyond.

Ying has been in business for more than 25 years during which time she has served as a financial controller in the US and Hong Kong, and as a high-level advisory consultant in China. She has performed extensive financial planning work, advised multinational corporations setting up manufacturing operations in China and conducted financial feasibility studies for foreign venture capital investments. Her industry experience covers computer, telecom components, integrated circuits, PCB, optical system, special materials, chemicals, medical products, food processing, beverages, auto components, wholesale, retail and professional services. As a corporate strategy consultant, Ying has also advised clients on competitive strategy and China market development.

Ying has hands-on experience in all aspects of operational process and is experienced in operational/financial audit to identify management control weakness, FCPA-style bribery concerns and fraud risks. She has worked on numerous pre-transactional due diligence projects and on complex fraud investigations at multinational operations in China. Her successes have included solving a supply chain fraud by establishing activity links to capture criminal evidence for a U.S. food manufacturer, and pinpointing weak HR policies as a threat to effective control for a European retailer. She also led a large-scale investigation into bribery and kickbacks at one of the world's top PC manufacturers, in which her evidence led to top-level dismissals and a thorough reorganisation.

Ying is a Certified Fraud Examiner (CFE) and holds an MBA from the John Anderson Graduate School of Management of the University of California Los Angeles (UCLA) as well as a Bachelor of Science from the School of Business of San Jose State University. She has served as Chairperson of the Transportation and Logistics Forum of the American Chamber of Commerce in China.

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ChinaWhys  
PEOPLE

Yingzeng  
Yu

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PETER HUMPHREY,  
YU YINGZENG  
CHINAWHYS COMPANY LTD

Plaintiffs,

V,

GLAXOSMITHKLINE PLC;  
GLAXOSMITHKLINE LLC

Defendants.

Case No. 2:16 cv 5924

**DECLARATION OF GLAXOSMITHKLINE PLC**

I, Simon Dingemans, being above 18 years of age and competent to make this declaration, hereby declare that:

1. My name is Simon Dingemans. I am aware and cognizant of the facts set forth in this Declaration and am able to swear, and I hereby do swear, that all of the matters contained in this Declaration are true and correct.

2. I am a Director of GlaxoSmithKline plc ("GSK PLC") and am currently appointed as the Chief Financial Officer of GSK PLC.

3. GSK PLC is a public limited company organized under the laws of England and Wales, with its principal place of business at 980 Great West Road, Brentford, Middlesex TW8 9GS, England. GSK PLC is not incorporated under the laws of the Commonwealth of Pennsylvania.

4. GSK PLC is a holding company only. GSK PLC was created and exists solely for the purpose of holding the stock of its subsidiaries, through several layers of wholly owned subsidiaries.

5. GSK PLC has never conducted commercial operations anywhere in the world, including the United States and the Commonwealth of Pennsylvania.

6. GSK PLC has never designed, developed, manufactured, marketed or sold any products or services anywhere in the world, including the United States and the Commonwealth of Pennsylvania.

7. GSK PLC is not and has never been a direct shareholder of GlaxoSmithKline LLC ("GSK LLC").

8. GSK PLC and GSK LLC maintain all the formalities of separate corporations. GSK PLC and GSK LLC do not maintain common books and records, payrolls, bank accounts, or boards of directors. GSK LLC and GSK PLC are separately and adequately capitalized.

9. GSK PLC and GSK China maintain all the formalities of separate corporations. GSK PLC and GSK China do not maintain common books and records, payrolls, bank accounts, or boards of directors. GSK PLC and GSK China are separately and adequately capitalized.

10. GSK PLC does not have operational headquarters in either Philadelphia, Pennsylvania or Research Triangle Park, North Carolina.

11. GSK PLC has never been licensed to do business in Pennsylvania.

12. GSK PLC has never been required to maintain, and has never maintained, a registered agent for service of process in Pennsylvania.

13. GSK PLC has no agents or employees in Pennsylvania.

14. GSK PLC owns no property, real or personal, in the Commonwealth of

Pennsylvania.

15. At least since 2013, GSK PLC has not acquired, disposed of, owned or leased any real property in Pennsylvania.

16. GSK PLC has never filed or been required to file a tax return within the commonwealth of Pennsylvania.

17. GSK PLC was not a party to the April 25, 2013 Consultancy Agreement, including all appendices, entered into between GSK China (Investment) Co. Ltd. ("GSK China") and ChinaWhys, through the ChinaWhys alter egos ChinaWhys (Shanghai) Consulting Co. Ltd. and ChinaWhys Co. Ltd., which is the subject of the within litigation.

18. None of the GSK-affiliated individuals who are referred to in the complaint that was filed in connection with this litigation ("Complaint") were employed by GSK PLC during the relevant time period (April through July 2013) set forth in the allegations:

- a. Mark Reilly;
- b. April Zhao;
- c. Jennifer Huang;
- d. Leslie Chang;
- e. Brian Cahill;
- f. June Soon; and
- g. Maggie Zheng.

19. On July 2, 2012, GSK LLC agreed to plead guilty and to pay \$3 billion to resolve criminal and civil liabilities arising from the promotion of certain prescription drugs, the failure to report certain safety data, and its civil liabilities for alleged false price reporting practices, arising from various conduct that occurred in the United States between 1994 - 2010 ("2012 U.S.

Settlement"). GSK PLC was not a party to the 2012 U.S. Settlement.

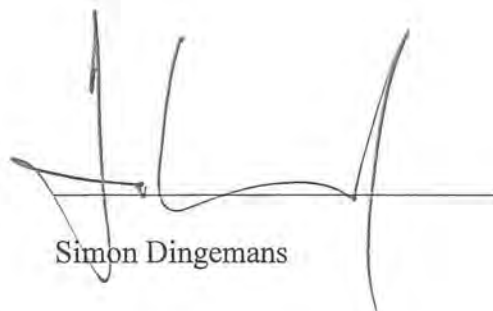
20. On September 19, 2014, the Changsha Intermediate People's Court in Hunan Province, China entered a judgment against GSK China for approximately \$489.5 million in connection with violations by GSK China personnel of Chinese law prohibiting bribery of non-governmental Chinese personnel ("2014 China Judgment"). GSK PLC was not a party to the 2014 China Judgment.

21. On September 30, 2016, the United States Securities and Exchange Commission ("U.S. SEC") and GSK PLC entered into a civil resolution concerning internal controls and recordkeeping provisions of the United States Foreign Corrupt Practices Act of 1977 relating to conduct in China by GSK China and a related joint-venture ("2016 U.S. Settlement"). Neither GSK LLC nor GSK China were parties to the 2016 U.S. Settlement.

\* \* \*

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

DATE: 13<sup>th</sup> January 2017



Simon Dingemans

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PETER HUMPHREY,  
YU YINGZENG  
CHINAWHYS COMPANY LTD

Plaintiffs,

V,

GLAXOSMITHKLINE PLC;  
GLAXOSMITHKLINE LLC

Defendants.

Case No. 2:16 cv 5924

**DECLARATION OF GLAXOSMITHKLINE LLC**

I, William Mosher, being above 18 years of age and competent to make this declaration, hereby declare that:

1. My name is William Mosher. I am aware and cognizant of the facts set forth in this Declaration and am able to swear, and I hereby do swear, that all of the matters contained in this Declaration are true and correct.
2. I am currently employed as Vice President & Associate General Counsel of GlaxoSmithKline LLC ("GSK LLC").
3. GSK LLC is a limited liability company organized in the state of Delaware, with corporate operations in Research Triangle Park, North Carolina and Philadelphia, Pennsylvania.
4. GSK LLC is an indirect wholly-owned subsidiary of GlaxoSmithKline PLC ("GSK PLC").

Exhibit

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5. GSK LLC and GSK PLC maintain all the formalities of separate corporations. GSK LLC maintains books and records, payrolls, bank accounts, and a board of directors independently of GSK PLC. GSK LLC and GSK PLC are separately and adequately capitalized.

6. At all relevant times (at least from 2001 – present) GSK LLC is not, and has not been, a direct or indirect shareholder of GlaxoSmithKline (China) Investment Co., Limited (“GSK China”).

7. At least from 2013 – present, GSK LLC has had no commercial operations in China.

8. None of the GSK-affiliated individuals who are referred to in the complaint (“Complaint”) that was filed in connection with this litigation were employed by GSK LLC or otherwise performed services on behalf of, or directed towards, GSK LLC during the relevant time period (April through July 2013) set forth in the allegations:

- a. Mark Reilly;
- b. April Zhao;
- c. Jennifer Huang;
- d. Leslie Chang;
- e. Brian Cahill;
- f. June Soon; and
- g.. Maggie Zheng.

9. GSK LLC was not a party to the April 25, 2013 Consultancy Agreement, including all appendices, entered into between GSK China (Investment) Co. Ltd. (“GSK China”) and ChinaWhys, through the ChinaWhys alter egos ChinaWhys (Shanghai) Consulting Co. Ltd. and ChinaWhys Co. Ltd., which is the subject of the within litigation.

10. On July 2, 2012, GSK LLC agreed to plead guilty and to pay \$3 billion to resolve criminal and civil liabilities arising from the promotion of certain prescription drugs, the failure to report certain safety data, and its civil liabilities for alleged false price reporting practices, arising from various conduct that occurred in the United States between 1994 - 2010 ("2012 U.S. Settlement"). Neither GSK China nor GSK PLC were parties to the 2012 U.S. Settlement.

11. On September 19, 2014, the Changsha Intermediate People's Court in Hunan Province, China entered a judgment against GSK China for approximately \$489.5 million in connection with violations by GSK China personnel of Chinese law prohibiting bribery of non-governmental Chinese personnel ("2014 China Judgment"). GSK LLC was not a party to the 2014 China Judgment.

12. On September 30, 2016, the United States Securities and Exchange Commission ("U.S. SEC") and GSK PLC entered into a civil resolution concerning internal controls and recordkeeping provisions of the United States Foreign Corrupt Practices Act of 1977 relating to conduct in China by GSK China and a related joint-venture ("2016 U.S. Settlement"). GSK LLC was not a party to the 2016 U.S. Settlement.

\* \* \*

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

DATE:

*January 13, 2017*



William Mosher



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**Register**

## Conviction of private investigators in China further complicates anti-corruption compliance efforts

**Blog** Government Enforcement Exposed

### Barnes & Thornburg LLP

**China, USA** | August 19 2014

The recent convictions of Peter Humphrey and his wife and business partner Yu Yingzeng demonstrate the risks corporate investigation firms face in China when they obtain or pass on information on Chinese citizens. But perhaps even more alarming for U.S. companies is the effect of such prosecutions on their efforts to comply with the Foreign Corrupt Practices Act and other anti-corruption laws, as these types of convictions stand to have a chilling effect on both companies' due diligence efforts and their internal investigations into allegations of bribery and fraud in China.

Mr. Humphrey, a British citizen, and Ms. Yu, a Chinese citizen, were convicted of trafficking in personal information of Chinese citizens between 2009 and 2013 through their company ChinaWhys. ChinaWhys, which still operates an up-to-date website, markets itself as "an international business risk advisory firm with eyes in China." It offers services from "due diligence and the discreet gathering of timely business intelligence, to the vetting of partners and the screening of employees." It specifically references corruption investigations on its website. Mr. Humphrey, himself a Certified Fraud Examiner, has written extensively on the issues facing companies in China, including under the anti-corruption laws, and the ways forensic firms can assist companies to comply with their legal obligations. ChinaWhys is one of many firms in China that seeks to assist companies in conducting background checks and other due diligence, which can be more difficult in China than in other jurisdictions.

Chinese officials claimed that Mr. Humphrey and Ms. Yu had, through ChinaWhys, illegally obtained the "personal household registrations" of Chinese citizens, or "hukous," as well as other personal information, for a price of \$130 to \$163 for each item, which they packaged into reports they sold at great profit. While it was not discussed at trial, ChinaWhys boasted many large multinational corporations as clients and may have been assisting those clients in Foreign Corrupt Practices Act compliance or investigations work. Mr. Humphrey was sentenced to two and one half years in prison (including one year served while awaiting trial) and a fine of £20,000, while Ms. Yu was sentenced to two years in prison and a £15,000 fine.

The convictions reflect the challenges companies can face in conducting and maintaining appropriate due diligence in China under the FCPA or other anti-corruption laws. Those laws require companies to investigate potential third-party consultants, agents and business partners to ensure, among other things, that they are not (and do not have improper relationships with) government officials. Companies are also encouraged to investigate allegations of anti-corruption violations swiftly and completely, and to self-report them to the authorities. The public prosecution of

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Exhibit

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individuals and companies in China for violating laws related to the collection of personal information is a deterrent to this type of diligence and reporting, because companies are now not only going to be hesitant to reach out to companies like ChinaWhys to assist in conducting due diligence, but they may also find that there are fewer companies out there in China that are willing to assist them. By enforcing laws against the collection and disclosure of personal information (allegedly often at the behest of Chinese individuals or companies that stand to lose from such a disclosure), China is imposing yet another roadblock for companies seeking to do business there. In this way, preventing access to background information may actually make it easier for individuals and entities get away with fraud, despite claims by Chinese authorities that the enforcement of privacy laws is meant to combat and root out corruption.

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**Barnes & Thornburg LLP** - Kathleen L. Matsoukas

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## Foreign couple arrested for selling personal information

08-27-2013 13:50 BJT

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Shanghai police have arrested a foreign couple for illegally obtaining information that infringed upon the privacy of Chinese citizens. This is the first case of foreigners being arrested for privacy infringement in China.

57-year-old Peter Humphrey, from Britain, and 60-year-old Yu Ying Zeng, from the United States, have confessed to breaching privacy laws.

In 2003, they registered Chinawhys Limited, a shell company in Hong Kong. It was the start of a ten year profitable -- but illegal -- business.

Just a year later, they registered another company in Shanghai, and hired a dozen employees.

Every year they earned profits as high as 6 million yuan from about 100 clients.

More than five hundred investigation reports were found among company records, some of them severely infringing on the privacy of Chinese citizens.

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驻外记者招聘启事  
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The celebrations are still continuing as the victorious coach, Joachim Loew, has been honored for his achievement in his hometown of Freiburg. Germany coach Loew honored in hometown of Freiburg

Chinese men's national team continued its preparation for next year's Asian Cup

Cas

Lu Wei with Criminal Invest, Division of Shanghai Public Security Bureau said, "These mainly include household registration information, vehicle and property information and exit-entry records."

Most of Humphrey and Yu's clients were transnational corporations, including manufacturing companies, financial institutions and law firms.

The couple obtained people's personal information at prices ranging from 800 to 2,000 Yuan.

Using that information, they then sold their investigation reports at more than 10,000 Yuan.

Suspect Peter Humphrey said, "We sometimes use illegal methods to obtain personal information, I very much regret doing this, and I want to apologize to the Chinese government."

The case is still under investigation.

Early in August, Shanghai police arrested 126 people for privacy infringement, 35 of whom are now under criminal detention.

## Related stories

China pledges more efforts to protect personal information 2013-08-13

1,213 arrested for personal information trafficking 2013-08-12

Editor: James | Source: CCTV.com

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they managed a one-all draw against visitors Jordan during a football friendly in Harbin, the capital city of Northeast

China's Heilongjiang Province.

China held to 1-1 draw by Jordan



The defending world champs came into the contest with a perfect 6-and-oh record, but they would be in for a tough first half before opening things up in the second.

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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PETER HUMPHREY, YU YINGZENG, and  
CHINAWHYS COMPANY LTD,

Plaintiffs,

v.

GLAXOSMITHKLINE PLC and  
GLAXOSMITHKLINE LLC,

Defendants.

---

Civil Action No.: 2:16-CV-5924

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO  
COMPEL ARBITRATION, OR, IN THE ALTERNATIVE,  
TO DISMISS THE COMPLAINT**

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Plaintiffs Peter Humphrey, Yu Yingzeng and ChinaWhys Company Ltd. respectfully submit this Memorandum in Opposition to Defendants' Motion to Compel Arbitration, or, in the Alternative, to Dismiss the Complaint. For the reasons set forth herein, both motions should be denied.<sup>1</sup>

### **PRELIMINARY STATEMENT**

This case arises out of a massive scheme by GlaxoSmithKline plc ("GSK PLC") and GlaxoSmithKline LLC ("GSK LLC") (together, "GSK" or "Defendants") to increase sales of drugs through, among other illicit practices, corrupt payments to doctors and other health care providers around the world, including in China. Multiple criminal and regulatory investigations in the United States and elsewhere have already led to billions of dollars in fines, criminal convictions of multiple employees, and on-going probationary-style supervision by multiple regulators, including the United States Department of Justice (the "DOJ") and the United States Securities and Exchange Commission (the "SEC"). As set forth in the Complaint, in an effort to hide the extent of the corruption, top GSK executives launched a campaign to prevent whistleblower complaints and evidence of bribery in China and other locations from seeing the light of day.

As part of that campaign, GSK lied to Plaintiffs, who became unwitting instruments of GSK's corrupt scheme to cover up the vast bribery it was engaged in in China. This occurred when GSK retained Plaintiffs under false pretenses to investigate a whistleblower who transmitted details about GSK's China-based corruption to senior GSK management and threatened to provide the information to the DOJ and other regulators. GSK told Plaintiffs, who operated an investigations firm specializing in foreign corrupt practices investigations for U.S.-

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<sup>1</sup> Pursuant to Local Rule 7.1(f), Plaintiffs respectfully request oral argument on these motions.

based companies, that the whistleblower's allegations were false and that the whistleblower was engaged in extortion. In fact, Defendants knew that the whistleblower's allegations were accurate and Defendants' true motive for engaging Plaintiffs was to discredit the whistleblower and cover up GSK's illegal scheme. As a direct result of Defendants' conduct, Plaintiffs Humphrey and Yu were arrested, summarily convicted, and imprisoned for two years in China under harsh, isolated conditions, unable to communicate with the outside world, during which time Humphrey developed cancer and was prevented from obtaining medical treatment. Plaintiffs also lost their valuable investigations business. Plaintiffs have asserted federal racketeering and conspiracy claims under RICO, as well as state law claims for fraud, intentional infliction of emotional distress, negligent infliction of emotional distress, and civil conspiracy.

Defendants seek to avoid facing the merits of Plaintiffs' claims with a pair of motions. Both motions are meritless and should be denied. Defendants first make the staggeringly cynical and legally baseless argument that Plaintiffs should *go back to China* to arbitrate these claims. Defendants rely on an arbitration clause in an agreement between two parties *neither of which is a party to this lawsuit*. They can point to no case in which a non-signatory to an arbitration agreement (which Defendants are) was permitted to compel another non-signatory to the arbitration agreement (which Plaintiffs are) to arbitrate its claims. That is reason enough to deny Defendants' motion. None of the bases offered by Defendants for compelling arbitration by a non-signatory against a signatory, or a signatory against a non-signatory, would be applicable here. Accordingly, under established precedents of this court and the Third Circuit, Defendants' motion must be denied. Moreover, even if Defendants could assert a basis to compel arbitration (and they cannot) Plaintiffs cannot be compelled to arbitrate in China, because Defendants' own

conduct has made it impossible for Plaintiffs Humphrey and Yu to enter China, and Plaintiffs therefore cannot, as a practical matter, pursue their claims there.

Defendants' motion to dismiss the Complaint is equally meritless. Defendants first argue that this Court cannot exercise personal jurisdiction over Defendant GSK PLC. That argument is baseless. GSK PLC is part of the GSK Group, which GSK describes as an integrated "global healthcare company." It maintains one of its three "headquarters" here in Pennsylvania, runs its legal department out of the United States, and conducts significant aspects of its global compliance function in Pennsylvania. Indeed, Defendants' centralized "drop box" for whistleblower claims as part of its "global compliance program" is in Pennsylvania. It is plainly "at home" here, and therefore subject to general personal jurisdiction. It is also subject to specific jurisdiction based on the numerous "suit-related" activities conducted here. The direct cause of Plaintiffs' injury was the Defendants' attempts to silence a whistleblower who directed allegations to Defendants *in the United States* and threatened to present them to U.S. authorities. Although the full picture will be revealed only through discovery, there can be no doubt that Defendants' efforts were directed in significant part from the United States.

Defendants' motion on the merits rests primarily on the argument that Plaintiffs "sued the wrong entities." This argument is based on a deliberate mischaracterization of the Complaint and supported by declarations – impermissible on a Rule 12(b)(6) motion to dismiss – asserting that the individuals who interacted directly with Plaintiffs are employed by legal entities other than the Defendants. The declarations are not only entirely improper, but also irrelevant. The allegations of the Complaint are that *Defendants* were engaged in a world-wide scheme to boost drug sales through illegal payments to doctors and health care providers, and facing investigations in the United States concerning conduct here and abroad, including in China.

*Defendants* – at GSK’s highest levels – *not* GSK China, received whistleblower allegations threatening to make this bribery scheme public and lied to Plaintiffs as part of an effort to cover up the allegations and prevent their discovery by regulators in the United States, which would have subjected (and ultimately did subject, when Defendants’ efforts failed) *Defendants* to liability here. Even if Defendants’ declarations were permitted on a 12(b)(6) motion (and they plainly are not) the fact (if true) that the individuals who interacted directly with the Plaintiffs in China were technically employees of GSK China would be wholly irrelevant.

Defendants also factually dispute the Complaint’s allegations that Plaintiffs Humphrey and Yu were arrested as a result of and in connection with their work for GSK citing articles from Chinese state media suggesting that Humphrey and Yu purportedly “confessed” to crimes and somehow deserved to be prosecuted. But a Rule 12(b)(6) motion is not the time to dispute the allegations of the Complaint, and certainly not by reference to Chinese state propaganda.

On Plaintiffs’ RICO claims, GSK makes the argument – which the Court of Appeals flatly rejected the last time GSK made it – that GSK is not liable for Plaintiffs’ damages because an “intermediary” – this time the Chinese authorities – put Plaintiffs Humphrey and Yu in prison. Equally baseless are Defendants’ arguments that the Complaint fails to allege a RICO pattern or agreement, an argument Defendants are only able to make by willfully ignoring the allegations of the Complaint. Similarly, Defendants rely on an inapplicable outlier case to claim that Plaintiffs lack standing to bring their RICO claims, while ignoring authority from this Circuit and other jurisdictions that undermine their argument.

Defendants’ arguments on Plaintiffs’ state law claims fail for at least the following reasons:

- The Court of Appeals has squarely rejected Defendants’ attempt to dismiss the fraud claim based on a “you got the wrong defendant” argument that relies on declarations that factually dispute the defendants’ involvement.
- Contrary to Defendants’ assertion, a claim for civil conspiracy does not require a showing of malice where, as here, the alleged underlying conduct was itself unlawful.
- Under established precedent, a plaintiff may – contrary to Defendants’ argument – claim damages for emotional distress resulting from his imprisonment against a party whose negligence led to the imprisonment, even though others (*i.e.*, the state) proximately caused the imprisonment.
- Defendants’ arguments based on the statute of limitations fail because they ignore (1) that the statute of limitations did not begin to run until Plaintiffs learned of the basis for their claims, (2) the parties’ tolling agreement and (3) that Plaintiffs’ imprisonment by a totalitarian state prevented them from pursuing their claims while they were in prison.

Finally, Defendants’ arguments under Federal Rule of Civil Procedure 19 fail because GSK China is not a necessary party – but rather at most a potential joint tortfeasor – and in any event dismissal would be inappropriate because Plaintiffs would otherwise have no remedy given that they cannot pursue these claims in China as a direct result of Defendants’ wrongdoing.

## **FACTUAL BACKGROUND<sup>2</sup>**

### **The Parties**

Plaintiffs Peter Humphrey and Yu Yingzeng are the founders of the investigations company ChinaWhys Company Ltd. (“ChinaWhys”) and were both leading anti-fraud professionals at the time of the events described in the Complaint. (Plaintiffs’ Complaint, filed in this Court on November 15, 2016, (No. 16-cv-5924, D.E. 1) (hereinafter, “Compl.”) ¶¶ 6-7.) ChinaWhys specialized in assisting U.S. and European law firms and businesses investigate and

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<sup>2</sup> Defendants have introduced hundreds of pages of factual material outside of the Complaint through the Declaration of Jayne Anderson Risk, including three additional declarations. It is axiomatic that the Court may not consider any of these materials on Defendants’ motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). *See* Federal Rule of Civil Procedure 12(d).

address compliance issues pertaining to anti-bribery regulations, including those set forth in the Foreign Corrupt Practices Act (“FCPA”). In particular, ChinaWhys assisted firms that were being investigated by regulators in the United States, including the DOJ and SEC. (*Id.* at ¶ 6.) At all times relevant to this matter, ChinaWhys had numerous pending engagements and contracts with law firms and businesses in the United States. As a result of Defendants’ actions, ChinaWhys lost significant revenue in the United States, and the ChinaWhys brand, goodwill and other assets were destroyed. (*Id.* at ¶ 9.)

Defendants are part of the GSK Group, which holds itself out as an integrated “global healthcare company.” (*See* Declaration of John Zach (hereinafter “Zach Decl.”) Exs. C and D.)<sup>3</sup> It has headquarters in Brentford, England; Philadelphia, Pennsylvania; and Durham, North Carolina. (*See* Compl. ¶ 10; Zach Decl. Ex. B.) The Group is managed as a single, integrated company that issues an Annual Report on behalf of the Group. (Zach Decl. Ex. C.) “The Directors of GlaxoSmithKline plc manage the risks of the Group at a group level, rather than at an individual business unit level.” (Zach Decl. Ex. F.) “The Directors of the Group manage the Group’s operations on a business sector basis.” (*Id.*) “The development, performance and position of the Group are discussed in the Group’s 2015 Annual Report.” (*Id.*) GSK Group is managed by a Group Board of Directors and Executive Team. (*See* Zach Decl. Ex. C.) GSK’s General Counsel, Dan Troy is based in the United States. (Zach Decl. Ex. A.)

GSK’s “Global Compliance function is responsible for supporting the development and implementation of practices that facilitate employees’ compliance with laws and Group policy.” (Zach Decl. Ex. E.) Its “Global Compliance Investigations co-ordinates all compliance-related

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<sup>3</sup> The Declaration of John Zach is offered in opposition to Defendants’ motion to dismiss for lack of personal jurisdiction, which (although Defendants nowhere cite the rule) is presumably made under Federal Rule of Civil Procedure 12(b)(2).

investigations, ensuring consistency and efficiency of investigations across geographies and business units.” (*Id.*)

GSK offers a “secure, offsite post office box” for any whistleblower submissions. (Zach Decl. Ex. E.) That mailbox is located in Philadelphia, Pennsylvania. (*Id.*) GSK list seven “Global Compliance Business Partners”, who, according to GSK, “are aligned to each business unit.” (*Id.*) “Their role is to proactively partner with senior leaders to drive a values and compliance-based culture and improve risk identification and management practices.” (*Id.*) Two of GSK’s Global Compliance Business Partners are based in the United States, with “215” area code telephone numbers. (*Id.*)

GSK’s General Counsel, Dan Troy, is based in the United States and manages the companies 400 lawyers based in Pennsylvania, New Jersey, North Carolina, Belgium and the UK. (Zach Decl. Ex. A.) As discussed further below, Troy “played an active role” in forming GSK’s response to the whistleblower’s revelations of corruption in China. (*Id.*)

### **GSK’s Ongoing Worldwide Bribery and Promotion Scheme**

This case is set against the background of various investigations into GSK’s criminal and illegal activities around the world by both criminal and civil regulatory authorities in the United States and elsewhere. (Compl. ¶ 15.) These investigations have revealed that GSK has been bribing doctors around the world by various means in order to increase the sale of their drugs. (*Id.* at ¶¶ 37, 116, 123.) This criminal and otherwise illegal conduct was thrown into sharp focus in 2012 when GSK entered into a settlement agreement with the DOJ. (*Id.* at ¶ 15.) As part of that agreement, GSK LLC pled guilty to three misdemeanor charges under the Food, Drug and Cosmetic Act, and agreed to pay \$3 billion in penalties and damages and was essentially placed on supervised release. (*Id.* at ¶¶ 15-17.) This was one of the largest health care fraud settlements

in the history of the United States. (*Id.* at ¶ 15.) Significantly, even at the time it was reached, the DOJ and other regulators were signaling that they believed this settlement was only the tip of the iceberg and that GSK may well have been conducting similar bribery schemes around the world. This is most clearly indicated in the plea agreement that GSK LLC signed with the DOJ, which expressly carves out “any investigations of GSK that are or may be conducted in the future by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the sales and marketing of GSK’s products to foreign customers.” (*Id.* at ¶ 21.) Among other things, by 2010 (years before GSK’s criminal plea), the DOJ and the SEC had already initiated an FCPA investigation into GSK’s pharmaceutical sales practices in China and other foreign nations, which were still ongoing. (*Id.* at ¶ 22.)

There is no doubt that GSK continued to operate an international bribery and promotion scheme even as the ink was drying on its multi-billion dollar DOJ settlement. Among other things, the SEC has since found that GSK’s China-based bribery and promotion activities extended to at least June 2013. (Declaration of Jayne Anderson Risk in Support of Defendants’ Motion to Compel Arbitration, or, in the Alternative, to Dismiss the Complaint (hereinafter “Risk Decl.”) Ex. 8 at 3.) In doing so, the SEC also found “deficiencies in GSK’s internal accounting controls and compliance program also led to instances of similar improper conduct in connection with sales in other countries in which GSK operates.” (*Id.* at 2.) Among other things, during this time period GSK spent nearly RMB 1.4 billion (USD \$225 million) on planning and travel services, much of which was actually paid out bribes. In addition, in or around this same time period, GSK set up a special “crisis management” team in order to bribe

Chinese regulators with money and gifts. All of this, and other bribes, were approved by Mark Reilly who headed up GSK's Chinese operations. (Compl. ¶ 25.)

Given the criminal and civil settlement that GSK reached with the DOJ in 2012, it was under tremendous pressure to avoid future scandals. Any additional finding of corruption would put GSK at risk of—among other things—harsher sanctions in the United States, further reputational harm, and significant harm to GSK's share price. Likewise, with U.S. regulators vowing to hold senior company officials accountable for corporate fraud, GSK's management well understood that they faced potential personal sanctions should future GSK misconduct be unearthed. (*Id.* at ¶ 26.)

#### **The China-based Whistleblower**

On January 16, 2013, approximately six months after GSK's settlement with the DOJ, an anonymous whistleblower sent an email entitled "Notification of Bribery by GSK in China" to GSK's Audit Committee, Board of Directors, Executive Management, including CEO Sir Andrew Witty, assorted media relations employees, and independent auditors at PwC. (Compl. ¶ 30.) The e-mail contained detailed corruption allegations relating to GSK's business in China that were strikingly similar to the conduct for which GSK had just paid penalties in the United States. This was also the type of misconduct that GSK had claimed to the DOJ it now had the controls in place to prevent. (*Id.* at ¶ 31.) In essence, the whistleblower asserted GSK "has engaged in illegal marketing and large-scale bribery to sell its products to Chinese hospitals and doctors." (*Id.* at ¶ 32.)

That email was followed on March 13, 2013 by another anonymous email (from a different email address) sent to GSK senior management claiming that Mark Reilly, the general manager of GSK China, received a bribe in the form of sexual relations in return for maximizing

business for China Comfort Travel (“CCT”). (Compl. ¶ 45.) The email went on to explain that CCT was an important part of the GSK bribery and promotion scheme because it facilitated a money laundering scheme in connection with the bribing of hospitals and doctors who prescribe GSK drugs to patients. (*Id.* at ¶ 46.) It further stated that CCT provided an assistant to Reilly for sex in exchange for boosting GSK’s business with CCT. At the conclusion of the email, the whistleblower threatened to provide this information to the DOJ. GSK’s top management continued to receive information from the whistleblower, who repeated the company should “make a full accounting to the Chinese regulatory authorities, the U.K.’s Serious Fraud Office, and the SEC and DOJ.” (*Id.* at ¶ 47.)

As has been publicly reported: “During the subsequent investigation, [GSK General Counsel Dan] Troy played an active role in advising the company’s management team on how best to engage with the authorities during this investigation. Alongside the official investigation, Troy hired an external legal firm, Ropes and Gray, to conduct an independent investigation into what had happened in China. ‘This was an attorney–client-privileged investigation reporting to me, with my reporting to the Board and GSK’s executive management team on their findings.’” (Zach Decl. Ex. A.) As described above, Dan Troy is based in the United States and directs the global legal function from here.

In April 2013, Plaintiffs met with GSK for the first time. (Compl. ¶¶ 49-50.) At the initial meeting, the GSK officials were led by a GSK lawyer, Brian Cahill. (*Id.* at ¶¶ 50-51.) The GSK officials described to Humphrey and Yu the whistleblower allegations that were sent to GSK global CEO Andrew Witty and other senior officials, including the global head of compliance and General Counsel, alleging that GSK used its travel agent to channel kickbacks to customers and doctors. (*Id.* at ¶ 54.) They also indicated that included with the email was a

video that showed Reilly having sex with a Chinese woman, who Reilly claimed was his “regular girlfriend.” (*Id.* at ¶ 55.) The GSK officials stated that they believed Vivian Shi, a former GSK government affairs director, had orchestrated what the GSK officials described as a “smear campaign” against GSK. (*Id.* at ¶ 51.) The “smear campaign” involved 23 emails sent to Chinese governmental entities throughout China as well as a letter to top GSK management alleging widespread corruption in GSK’s Chinese pharmaceutical and vaccine businesses, with the direct approval of senior management. (*Id.*) The GSK officials claimed all of these allegations had been investigated and were false. (*Id.* at ¶ 59.) They further claimed Shi was disgruntled and trying to extort the company and using her deep connections with the Chinese government to defame the company and stimulate unwarranted regulatory scrutiny. (*Id.* at ¶ 52.)

During the April 15 meeting, Peter Humphrey asked GSK officials for copies of the anonymous whistleblower allegations, but GSK refused to provide them. (Compl. ¶ 56.) Instead, the GSK officials stressed that GSK had improved its compliance mechanisms following earlier corruption and other illegal activities that led to the DOJ settlement. (*Id.* at ¶ 57.) In particular, GSK referred to a whistleblowing system it established as a concrete step to show the DOJ how seriously it was taking corruption. GSK officials also stressed the development of a “compliance culture” to satisfy the DOJ and indicated that GSK had since “found more incidents of theft from the company rather than violation of compliance.” This was, of course, false. GSK knew full well at this time that the bribery scheme had occurred. (*Id.* at ¶ 58.) Nonetheless, the GSK officials reiterated to Humphrey that, in terms of the whistleblower’s allegations, “there is nothing there,” claiming they had uncovered only minor irregularities, like a license issue in Beijing that resulted in a negligible fine. This statement was knowingly false. (*Id.* at ¶ 60.)

Plaintiffs accepted the GSK officials' representations that they had thoroughly investigated the whistleblower allegations and that there was "nothing there." (Compl. ¶ 52.) Under this assumption, Humphrey and Yu understood that undermining the purported "smear campaigner's" credibility and determining the extent of her connections and influence would be essential to limiting the efficacy of her extortion. (*Id.* at ¶ 63.) Then, on June 12, 2013, The Wall Street Journal published an article about the anonymous whistleblower's allegations. (*Id.* at ¶ 71.) The article included the following statement from a GSK spokesperson: "Over the last four months we have used significant resources to thoroughly investigate each and every claim from this single, anonymous source and have found no evidence of corruption or bribery in our China business." (*Id.* at ¶ 78.) This is, of course, exactly what the GSK officials told Plaintiffs. (*Id.* at ¶ 52.)

GSK senior legal counsel Jennifer Huang later asked ChinaWhys to investigate the Public Security Bureau (PSB) and to "prepare an Organic analysis ASAP on the Chinese political regime, particularly on Chinese Communist Party Regime, PSB, and state council with official's name identified." (Compl. ¶ 82.) Humphrey and Huang had a phone call that same day, while Humphrey and Yu were in the United States. Huang said she wanted to investigate the PSB "to find out who's who in the investigation." (*Id.* at ¶ 83.) Humphrey became concerned that GSK was seeking to obstruct the investigation by Chinese authorities and replied that he could not do anything that could be deemed as violating state secrets and thus could only use public information for his research. (*Id.*)

On July 1, while Humphrey and Yu were still in the United States, GSK China's head of business development, Leslie Chang, asked Humphrey to investigate various government organs. (Compl. ¶ 84.) Humphrey refused. (*Id.* at ¶ 85.)

On July 10, 2013, Shanghai police raided ChinaWhys' Shanghai office and the home Humphrey and Yu shared in Beijing. (Compl. ¶ 91.) Both Humphrey and Yu were detained. (*Id.*) During their processing, a police officer told Humphrey: "This was ordered from above. This is related to GSK." (*Id.*) Around the same time, four senior GSK China executives were also arrested. (*Id.* at ¶ 108.) In response, GSK's global CEO, Sir Andrew Witty claimed, that GSK's head office in London lacked knowledge of the whistleblower's allegations and "had no sense of this issue." (*Id.*) This was untrue. The previous month, GSK admitted that had "a sense" of the issue, since it announced that its "four-month internal investigation into allegations of bribery and corruption in China found 'no evidence of corruption or bribery in our Chinese business.'" (*Id.* at ¶ 109.)

Approximately a year later, while Humphrey and Yu were detained and still awaiting trial, GSK issued a "Statement in Response to Recent Media Coverage Related to Our China Business." (*Id.* at ¶ 112.) The statement claimed that GSK had investigated "allegations made in early 2013 about GSK's business in China . . . over several months with the support of external legal and audit advice" and that, with the exception of minor expense claims fraud, "this investigation did not find evidence to substantiate the specific allegations made in the whistleblower emails." (*Id.*) GSK further stated that its China business "hired ChinaWhys in April 2013 to conduct an investigation following a serious breach of privacy and security," that was the Reilly sex tape, but that ChinaWhys was "not hired to investigate the substance of the allegations of misconduct made by the whistleblower." (*Id.* at ¶ 113.) This statement was misleading at best since the "breach of privacy and security" was actually a whistleblower reporting directly on the corruption allegations and Plaintiffs were dispatched to undermine her credibility and determine the extent of her connections and influence would be essential to

limiting the efficacy of her supposed extortion. (*Id.* at ¶¶ 63, 113.) This misleading statement by GSK prolonged Humphrey and Yu’s incarceration, because British diplomats attempting to intervene on Humphrey and Yu’s behalf did not have accurate information about what had led to their arrest. (*Id.* at ¶ 114.) An article published in *The Telegraph* on July 6, 2014 quotes a British official involved in efforts to intervene on behalf of Yu and Humphrey: “GSK refused to reveal the reasons why they had originally employed [Humphrey’s] services and that this impeded British attempts to intervene on his behalf.” He went on say “GSK were really cagey. They just kept saying it was routine work and kept the information deliberately vague. When we went to the Chinese we were arguing with one hand tied behind our backs.” (*Id.* at ¶ 115.)

On September 19, 2014, GSK issued a Statement of Apology to the People of China in which it announced that “GSK China Investment Co. Ltd (GSKCI) has been identified according to Chinese law to have offered money or property to non-government personnel in order to obtain improper commercial gains, and has been found guilty of bribing non-government personnel.” GSK was fined \$492 million for its bribery activities in China “in the biggest such penalty ever imposed by a Chinese court.” (Compl. ¶ 116.) Mark Reilly, the CEO of GSK China, was convicted for his part in the bribery scheme and sentenced to three years prison with a four-year reprieve and ordered deported, meaning he will never serve his sentence. (*Id.* at ¶ 117.) Four Chinese nationals were also given prison sentences along with reprieves, meaning they would never actually serve time in jail. (*Id.* at ¶ 118.) GSK’s also apologized “for the harm caused to individuals who were illegally investigated by GSKCI.” (*Id.* at ¶ 119.)

On September 30, 2016, GSK PLC entered into a settlement agreement with the SEC relating to its bribery scheme in China. (Compl. ¶ 120.) GSK PLC agreed to pay the SEC \$20 million in addition to what it paid to the Chinese authorities. In connection with that SEC

settlement, GSK PLC must also make regular reports to show it is overhauling its lax internal controls and is instituting basic safeguards to prevent corruption going forward. (*Id.*)

For their own part, as detailed in the Complaint, Plaintiffs Humphrey and Yu were summarily convicted and imprisoned in China under harsh conditions for almost two years, where they were denied fresh air and proper medical treatment, and were unable to see their teenage son or communicate with the outside world. While in confinement, Humphrey developed prostate cancer, for which he did not receive proper treatment and as a result the cancer became life-threatening. (Compl. ¶¶ 95-105.) In addition, Plaintiffs lost the entire value of their profitable investigations business. (*Id.* at ¶ 113.)

Following their release from prison, Humphrey was deported from China and prohibited from reentering the country for a period of ten years. (Declaration of Peter Humphrey, attached to Zach Decl. as Exhibit D, (hereinafter “Humphrey Decl.”) ¶ 2.)<sup>4</sup> Yu was not formally banned from China, but would not be granted a visa to return given the foregoing events. (*Id.*)

## **ARGUMENT**

### **I. DEFENDANTS CANNOT COMPEL PLAINTIFFS TO ARBITRATE THEIR CLAIMS IN CHINA**

Defendants seek to compel Plaintiffs to arbitrate their claims in China based on an arbitration agreement that was never signed by any of the parties to this dispute. (*See* Risk Decl. Ex. 1.)<sup>5</sup> As set forth below, Defendants fail to show they are entitled to invoke an arbitration agreement in these circumstances, which the Third Circuit has referred to as “uncharted waters.” *Invista S.A.R.L. v. Rhodia, S.A.*, 625 F.3d 75, 85 (3d Cir. 2010). In addition, the Court should not

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<sup>4</sup> The Declaration of Peter Humphrey is offered exclusively in opposition to Defendants’ motion to compel arbitration.

<sup>5</sup> The Consultancy Agreement on which Defendants seek to rely was between ChinaWhys (Shanghai) Ltd. and GSK China (Risk Decl. Ex. 1,) neither of which are parties to this lawsuit.

compel Plaintiffs to arbitrate their claims in China because to do so would result in manifest injustice, given that as a result of Defendants' conduct Plaintiffs now cannot safely enter China to arbitrate there.

**A. Defendants Fail to Establish They May Invoke An Arbitration Agreement to Which Neither Plaintiffs Nor Defendants Are Signatories**

In deciding whether to compel arbitration, “the party opposing arbitration is given the benefit of all reasonable doubts and inferences that may arise.” *Griswold v. Coventry First LLC*, 762 F.3d 264, 270 (3d Cir. 2014) (citing *Kaneff v. Del. Title Loans*, 587 F.3d 616, 620 (3d Cir. 2009)). Moreover, although there is a presumption of arbitrability as to disputes between *the parties* to a written agreement to arbitrate, “the presumption of arbitrability has never been extended to claims by or against non-signatories.” *Miron v. BDO Seidman, LLP*, 342 F. Supp. 2d 324, 332 (E.D. Pa. 2004). Defendants are not signatories of the arbitration agreement they present, a fact they finally acknowledge on page 19 of their brief. (Br. at 19.) Neither are any of the Plaintiffs. (*See* Risk Decl. Ex. 1.) Accordingly, there is no presumption of arbitrability applied to Plaintiffs' claims, and Defendants cannot meet their burden to establish a basis to compel arbitration.

Defendants face two insurmountable hurdles in seeking to compel arbitration because they must establish that they, as non-signatories to the arbitration agreement, can compel arbitration, and that Plaintiffs, who are likewise non-signatories to the arbitration agreement can be compelled to arbitrate their claims. Defendants cite no authority to support their “novel” argument, and the Court should not venture into these “uncharted waters.” *Invista S.A.R.L.*, 625 F.3d at 85 (“Not surprisingly, [defendant] offers no authority for its contention that a non-signatory to an arbitration agreement can compel another non-signatory to arbitrate certain

claims, and we have found none.”) This alone is reason to deny Defendants’ attempt to compel Plaintiffs to arbitrate.

**1. Defendants, as Non-Signatories, Cannot Establish a Basis to Compel Plaintiffs to Arbitrate**

With respect to the first hurdle, *i.e.*, that Defendants as non-signatories of the arbitration agreement may enforce it against Plaintiffs, the *only* basis Defendants offer for their position is equitable estoppel. (Br. at 19-20.) As the court explained in *Bannett v. Hankin*, 331 F. Supp. 2d 354, 359 (E.D. Pa. 2004), cited by Defendants (Br. at 20,) this estoppel theory, sometimes referred to as “alternative estoppel” “applies when a signatory to the written agreement must rely on the terms of the agreement to assert its claims against the nonsignatory such that the signatory’s claims make reference to or presume the existence of the written agreement, or the signatory’s claims arise out of and relate directly to the written agreement.” *Id.* at 359-360. Applying that principle, the court held that the defendants had standing to invoke an arbitration agreement against a signatory under an estoppel theory even though they were non-signatories to the arbitration agreement because the compensatory damages sought by the plaintiff were “allegedly due to him under” the terms of the contract containing the arbitration clause. *Id.* at 360.

As the court held in *Devon Robotics v. Deviedma*, No. 09-cv-3552, 2009 WL 4362822, at \*4 (E.D. Pa. Nov. 30, 2009), the “essential question in situations such as these is whether plaintiffs would have an independent right to recover against the non-signatory defendants even if the contract containing the arbitration clause were void.” The “plaintiff’s *actual dependence on the underlying contract* in making out the claim against the nonsignatory defendant is therefore always the *sine qua non* of an appropriate situation for applying equitable estoppel.” *Id.* (emphasis added.) Here, Plaintiffs’ Complaint does not even mention the Consultancy

Agreement that Defendants seek to enforce against Plaintiffs, much less rely on the terms of the agreement to assert their claims. In contrast to *Bannett*, Plaintiffs do not seek payments due to them under the Consultancy Agreement or otherwise assert any claim under the agreement. Nor do their claims arise out of any obligations or duties of the Defendants under the contract. Plaintiffs seek damages resulting from Defendants' tortious conduct in seeking to fraudulently cover up their own wrongdoing to avoid prosecution in the United States. Defendants are not even mentioned in the contract. The estoppel theory on which Defendants rely therefore would not apply here even if Plaintiffs were signatories, and they undisputedly are not. *See Devon Robotics*, 2009 WL 4362822, at \*4; *see also White v. Sunoco Inc.*, 189 F. Supp. 3d 486, 495 (E.D. Pa. 2016) (refusing to apply estoppel to compel signatory plaintiff to arbitrate fraud claims "not breach of contract (as might be expected if he were relying on the Agreement)" against non-signatory where plaintiff alleged he was fraudulently induced by defendant to obtain a credit card and signed a Cardholder Agreement containing a broad agreement to arbitrate); *Just B. Method, LLC v. BSCPR, LP*, No. 14-1516, 2014 WL 5285634 at \*9 (E.D. Pa. Oct. 14, 2014) (refusing to compel signatory plaintiff to arbitrate claims against non-signatory defendants because the non-signatory defendants "have no obligations and/or duties under the Agreement.")

Even if the claims were "intertwined" with the Consultancy Agreement, as Defendants argue, that alone would not permit enforcement by Defendants. While a finding that a plaintiff's claims are "intertwined" with the contract is a *necessary* condition to apply equitable estoppel to compel a signatory to arbitrate claims against a non-signatory, it is not a *sufficient* condition. For estoppel to apply, the party seeking to compel arbitration must establish "*a relationship among the parties which either supported the conclusion that [the party opposing arbitration] had consented to extend its agreement to arbitrate to [the non-signatory], or, otherwise put, made it*

inequitable for [the party opposing arbitration] to refuse to arbitrate on the ground that it had made no agreement with [the non-signatory]”. *Ross v. Am. Express Co.*, 547 F.3d 137 (2d. Cir. 2010) (quoting *Sokol Holdings, Inc. v. BMB Munai, Inc.*, 542 F.3d 354, 359 (2d. Cir. 2008) and overturning district court’s grant of defendant’s motion to compel arbitration based on equitable estoppel) (internal quotation marks omitted, emphasis and alterations in original). Defendants have not shown either that Plaintiffs claims are based on any agreement containing an arbitration clause or that even if such an agreement existed, the relationship among the parties supports the conclusion that Plaintiffs consented to extend that agreement to Defendants.

## **2. Defendants Cannot Enforce the Arbitration Agreement Against Plaintiffs, Who Are Themselves Non-Signatories**

In light of the foregoing, Defendants cannot establish their right to enforce the agreement against Plaintiffs. However, Defendants’ motion fails for the independent reason that Defendants cannot establish their right to compel arbitration *against Plaintiffs* because Plaintiffs also are not signatories to the arbitration agreement. In seeking to mount this second hurdle, Defendants argue that the Plaintiffs may be compelled to arbitrate “due to their affiliation with ChinaWhys (Shanghai), which is the signatory to the consultancy agreement.” (Br. at 20.) Again, Defendants are in uncharted waters. *Invista S.A.R.L.*, 625 F.3d at 85.

Not only is there no authority supporting the “novel” proposition that non-signatories can compel other non-signatories to arbitrate, *id.*, Defendants seek to bind Plaintiffs Humphrey and Yu based on theories of agency and estoppel that would not apply even if Defendants were parties to the contract they seek to enforce. As a threshold matter, as noted *supra*, “[t]he presumption in favor of arbitration does not extend . . . to non-signatories to an agreement.” *Griswold*, 762 F.3d at 271; *see also Devon Robotics*, 2009 WL 4362822, at \*4 (same); *Miron*, 342 F. Supp. 2d at 332 (“Because arbitration is a matter of contract, exceptional circumstances

must apply before a court will impose a contractual agreement to arbitrate on a non-contracting party.”).

Defendants assert two theories for seeking to enforce the arbitration agreement against Plaintiffs Humphrey and Yu—agency and estoppel. (Br. at 21.) With respect to Defendants’ agency argument, Defendants cite no case, and we are aware of no case, holding that *non-signatory plaintiffs* may be compelled to arbitrate under an agency theory. *Cf. Pritzker v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 7 F.3d 1110, 1121 (3d Cir. 1993) (cited in Br. at 21) (holding that claims by signatories *against* agents of party to arbitration agreement could be compelled to arbitration). Indeed, the authority is directly to the contrary. *Bel-Ray Co., Inc. v. Chemrite (Pty) Ltd.*, 181 F.3d 435, 444-45 (3d Cir.1999) (distinguishing *Pritzker* and refusing to compel non-signatory individuals to arbitrate claims under an agency theory). That is because arbitration can only be compelled when a party has contractually agreed to arbitrate, and here there is no evidence that Humphrey or Yu agreed to arbitrate anything. *See id.* (“Arbitration is strictly a matter of contract. If a party has not agreed to arbitrate, the courts have no authority to mandate that he do so.”).

With regard to Defendants’ estoppel argument (Br. at 21-22), courts have permitted signatories to compel arbitration against non-signatories when the non-signatories sought to “reap the full benefits” of the contract – *i.e.*, recover under the contract – containing the arbitration clause. *See Just B. Method*, 2014 WL 5285634, at \*9 (Plaintiff “cannot embrace certain favorable provisions and ignore or denounce the arbitration clause”) (cited in Br. at 22.) Here, Plaintiffs certainly have not reaped, and do not seek to reap any benefits from the contract. To the contrary, they have suffered only harm. Accordingly, even if the Defendants were signatories to the arbitration agreement they would not be justified in seeking to enforce the

agreement against Plaintiffs Yu and Humphrey under estoppel principles because Plaintiffs are not seeking recovery under the Consultancy Agreement.

Defendants also argue that the arbitration agreement may be enforced against Plaintiff ChinaWhys under principles of (1) alter ego, (2) agency and (3) assumption of contract rights. (Br. at 22-23.) The only case Defendants cite for their alter ego theory, *Aluminium Bahrain B.S.C. v. Dahdaleh*, F. Supp. 3d 461, 471 (W.D. Pa. 2014) refused to apply alter ego to require a non-signatory to arbitrate, because “[a]lter ego liability attaches only where it can be demonstrated that in all aspects of the business, the two corporations actually functioned as a single entity and should have been treated as such” and in that case the pleadings “did not address any of the alter ego factors.” *Id.* (quoting *Pearson v. Component Tech. Corp.*, 247 F.3d 471, 484–85 (3d Cir.2001) (internal quotation marks omitted)). The same analysis applies here—Plaintiffs’ Complaint does not establish the alter ego factors that would make the arbitration agreement enforceable against ChinaWhys.

In support of their agency theory, Defendants again cite *Pritzker*. (Br. at 23.) However, as noted above, *Pritzker* does not support the application of agency theory against a non-signatory plaintiff. (See Section A.2., *supra*.) Indeed, the law is clear that agency principles cannot be used to require non-signatories to arbitrate. *Bel-Ray Co., Inc.*, 181 F.3d at 444.

Finally, Defendants assert that Plaintiff ChinaWhys can be bound to the arbitration agreement because its personnel were involved in performing activities under the Consultancy Agreement. (Br. at 23.) This argument misconstrues the law. The question is not whether ChinaWhys was somehow involved in the contract, but whether it assumed the obligation *to arbitrate*. See *Thomson-CSF, S.A. v. Am. Arb Ass’n*, 64 F.3d 773, 777 (2d Cir. 1995) (cited in Br. at 23) (refusing to compel arbitration under assumption of obligation theory). Thus, for

example, non-signatories have been compelled to arbitrate where they sent a representative to participate in the arbitration process. *See Gvozdenovic v. United Air Lines, Inc.*, 933 F.2d 1100, 1105 (2d Cir. 1991) (flight attendants manifested a clear intention to arbitrate by sending a representative to act on their behalf in arbitration process). Here, there is nothing to suggest that Plaintiff ChinaWhys ever manifested an intent *to arbitrate*, and it therefore cannot be compelled to do so. *See Bel-Ray Co., Inc.*, 181 F.3d at 444.

Again, to be clear, the Court need not even address whether the arbitration clause can be asserted against the Plaintiffs as non-signatories, because the Defendants have failed to establish their right to assert the agreement at all given that they themselves are not signatories, as established above. However, even if the Court considers whether Plaintiffs as non-signatories can be compelled to arbitrate the answer is clearly that they cannot.

#### **B. The Court Should Not Compel Plaintiffs to Arbitrate In China**

Defendants also argue that Plaintiffs may be compelled to arbitrate in China despite the fact that, as alleged in the Complaint, Humphrey and Yu were deported from China. (Br. at 23-24.) In particular, Defendants argue that Humphrey and Yu's deportation is no impediment to arbitration because CIETAC rules allow a party to be represented by an authorized representative. (*Id.*) This argument misses the point entirely. Humphrey and Yu are obviously key witnesses in their own case. As a term of Humphrey's deportation, he is banned from entering China for a period of ten years. (Humphrey Decl. ¶ 2.) Although Yu was not technically banned from entering China, it is almost certain that she would not be granted a visa because of the sequence of events triggered by GSK's conduct. (Humphrey Decl. ¶ 3.) GSK's Mark Reilly, another likely witness, was also banned from entering China for ten years as a term of his deportation. Moreover, even if Humphrey and Yu were *legally* able to enter China, they cannot do so *safely*. (Humphrey Decl. ¶ 4.)

Accordingly, as a practical matter, Plaintiffs simply cannot pursue their claims in China. Under basic contract principles, a party cannot be compelled to perform an obligation that it has become impractical as a result of circumstances that were not anticipated at the time of contract. Restatement (Second) Contracts § 261 (1981) (“Where, after a contract is made, a party’s performance is made impracticable without his fault by the occurrence of an event the non-occurrence of which was a basic assumption on which the contract was made, his duty to render that performance is discharged, unless the language or the circumstances indicate the contrary.”); *see also U.S. Claims, Inc. v. Yehuda Smolar, PC*, 602 F. Supp. 2d 590, 600 (E.D. Pa. 2009) (setting out the requirements of discharge by reason of impracticability). Here, there can be no question that Plaintiffs did not anticipate and could not have anticipated that they would be imprisoned and eventually deported from China. Nor can it be said that Plaintiffs somehow agreed to be bound by the arbitration agreement even if they were deported. In addition, failure to excuse performance would result in a grave injustice, because it would result in the effective surrender of Plaintiffs’ claims.

The injustice that would result is made all the more acute by the fact that, according to the Complaint – the allegations of which must be accepted as true on Defendants’ motion to compel arbitration, *Just B. Method*, 2014 WL 5285634 at \*3, Plaintiff Humphrey and Yu’s deportation was the result of Defendants’ own wrongful conduct. Basic principles of equity, including the doctrine of unclean hands, preclude Defendants from enforcing the arbitration agreement against Plaintiffs where Defendants own wrongful conduct brought about Plaintiffs’ inability to perform. *See Mente Chevrolet Oldsmobile, Inc. v. GMAC*, 451 Fed. App’x. 214, 217 (3d Cir. 2011) (upholding jury decision not to enforce forbearance agreement based on defendant’s unclean hands).

## II. THE COURT HAS PERSONAL JURISDICTION OVER GSK PLC

The Defendants' argument that the Court does not have personal jurisdiction over GSK PLC (Br. at 24-25) is wrong. For the reasons set forth below, this Court has both general and specific jurisdiction over GSK PLC.

### A. The Court Has General Jurisdiction Over GSK PLC

The Supreme Court has described the “paradigm forum for the exercise of general jurisdiction” as “one in which the corporation is fairly regarded as at home.” *Goodyear Dunlop Tires Operations S.A. v. Brown*, 564 U.S. 915, 924 (2011). In other words, “[a] court may assert general jurisdiction over foreign (sister-state or foreign-country) corporations to hear any and all claims against them when their affiliations with the State are so ‘continuous and systematic’ as to render them essentially at home in the forum State.” *Id.* at 919. However, “*Goodyear* did not hold that a corporation may be subject to general jurisdiction *only* in a forum where it is incorporated or has its principal place of business; it simply typed those places paradigm all-purpose forums.” *Daimler AG v. Bauman*, 134 S. Ct. 746, 760 (2014) (emphasis added).

Here, GSK PLC openly acknowledges that it is “at home” in the present forum. For example, GSK’s website states that “[o]ur global headquarters are in the UK but we also have a significant presence in the USA.” (Zach Decl. Ex. B.) The website then goes on to list GSK’s “headquarters,” as being in Middlesex, U.K., Philadelphia, PA and North Carolina. (*Id.*) In contrast, GSK has well over two hundred subsidiaries throughout the world, with various “regional headquarters,” (*Id.*, Ex. B (noting “regional headquarters” in Singapore)), and none of those are listed as one of GSK’s “headquarters”. (See Zach Decl. Ex. C, 2015 Annual Report at 205, 250-258.) That designation is reserved for the three locations described on the website.

The fact that GSK PLC is “at home” in this forum is underscored by how its core operations are spread among those three “headquarters.” For example (and of particular

significance to this case), at GSK, “the Global Compliance function is responsible for supporting the development and implementation of practices that facilitate employees’ compliance with laws and Group policy.” (Zach Decl. Ex. E.) GSK’s “Global Compliance Investigations coordinates all compliance-related investigations, ensuring consistency and efficiency of investigations across geographies and business units.” These functions are managed by both the U.K. and the Philadelphia headquarters. For example, GSK and its Global Compliance Function offer a single “secure, offsite post office box” for any submissions that a potential whistleblower wants to make. (Zach Decl. Ex. E.) That mailbox is located in Philadelphia, Pennsylvania. Likewise, there are seven “Global Compliance Business Partners”, who, according to GSK, “are aligned to each business unit. Their role is to proactively partner with senior leaders to drive a values and compliance-based culture and improve risk identification and management practices.” (*Id.*) Two of them are based in the U.S., with “215” area code (Philadelphia-area) telephone numbers. (*Id.*)

As another example, GSK PLC’s General Counsel, Dan Troy, a member of GSK PLC’s Corporate Executive Team<sup>6</sup>, is based in the United States, from where he manages GSK’s legal team both in the U.S. and abroad.<sup>7</sup> (Zach Decl. Ex. A.) Maintenance by a corporate executive even of a *temporary* office within the forum has been held to justify the exercise of general

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<sup>6</sup> “Throughout the year, the General Counsel of the Group, as head of the Group’s legal function, and the Senior Vice President and Head of Global Litigation for the Group, who is responsible for all litigation and government investigations, routinely brief the Chief Executive Officer, the Chief Financial Officer and the Board of Directors on the significant litigation pending against the Group and governmental investigations of the Group.” (Zach Decl. Ex. C, 2015 Annual Report at 71.)

<sup>7</sup> As discussed further below, when a plaintiff asserts a federal claim, the relevant forum for the analysis of personal jurisdiction is the United States as a whole. *In re Automotive Refinishing Paint*, 229 F.R.D. 482, 487 (E.D. Pa. 2005) (“[I]n a federal court action arising under federal law, the proper forum for assessing minimum contacts is the United States as a whole.”).

personal jurisdiction. *See Perkins v. Benguet Consol. Min. Co.*, 342 U.S. 437, 447-448 (1952) (Ohio court's exercise of general jurisdiction permissible where the president of the foreign defendant temporarily “maintained an office,” “drew and distributed ... salary checks,” used “two active bank accounts,” “supervised ... the rehabilitation of the corporation’s properties in the Philippines,” and held “directors’ meetings,” in Ohio); *see also Daimler AG*, 134 S. Ct. 746 (describing *Perkins* as “the textbook case of general jurisdiction appropriately exercised over a foreign corporation that has not consented to suit in the forum.”).<sup>8</sup> *A fortiori*, the permanent location of a corporate officer in the forum, particularly when many of those reporting to the officer also live and work in the forum, justifies the exercise of personal jurisdiction.

Accordingly, GSK PLC is “at home” in this forum and the Court has general jurisdiction over it.

#### **B. The Court Has Specific Jurisdiction Over GSK PLC**

Even if GSK is not subject to general jurisdiction in this forum, the Court certainly has specific jurisdiction over this matter. The Supreme Court has explained that, even where a defendant is not subject to general jurisdiction, it can be subject to specific jurisdiction where “the defendant’s suit-related conduct” creates “a substantial connection with the forum.” *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014). Where, as here, the plaintiff asserts federal claims<sup>9</sup>, the

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<sup>8</sup> GSK PLC’s declaration proves both too much and not enough at the same time. For example, GSK argues that GSK PLC does not conduct any operations in the United States (Br. at 24), but then also asserts that it does not conduct any operations anywhere. (GSK PLC Declaration ¶ 5.) It further claims that its principal place of business is in Middlesex, England (*Id.* at ¶ 3,) but then states that it does not conduct any business at all and exists purely for the purpose of holding stock in its subsidiaries (which presumably do conduct business). (*Id.* at ¶ 4.) On the other hand, it carefully states that it does not have “operational” headquarters in either Philadelphia, Pennsylvania or Research Triangle Park, North Carolina (*id.* at ¶ 10), which only begs the question as to what type of headquarters it *does* have in the United States.

<sup>9</sup> The Court can exercise supplemental personal jurisdiction over Plaintiffs’ related state law claims. *Am. Trade Partners, L.P. v. A-1 Int’l Importing Enter., Ltd.*, 755 F. Supp. 1292, 1303 (E.D. Pa. 1990) (“Since

relevant forum is the United States as a whole. *In re Automotive Refinishing Paint*, 229 F.R.D. 482, 492 (E.D. Pa. 2005) (finding personal jurisdiction over Belgian entity where “it would appear that Plaintiffs’ antitrust claims arise, at least in part, out of [Belgian entity’s] contacts with the United States.”) Furthermore, “[b]ecause an incorporated organization is a “legal fiction,” the question of whether it has made [sufficient] contacts justifying the exercise of personal jurisdiction is, in reality, a question of whether the contacts made by the agents and employees of the corporation are sufficient to justify the exercise of jurisdiction.” *Id.* (internal quotation marks and citations omitted). There are numerous such contacts in this case including both conduct that occurred in the United States and communications directed to the United States:

- This case broadly arises out of GSK’s bribery and promotion scheme and the attendant corruption investigation by the DOJ and the SEC in the United States. (Compl. ¶ 22, 31.)
- More specifically, the whistleblower emails that directly led to Plaintiffs’ involvement threatened to disclose the bribery scheme in China to the DOJ and the SEC in the United States. Those emails were received in the United States. (Compl. ¶¶ 109-111.)
- Although discovery will reveal the full extent of the involvement of U.S.-based personnel in the cover-up in which Plaintiffs were ensnared<sup>10</sup>, it is clear that GSK’s General Counsel, who is based in the U.S., was substantially involved in directing GSK’s response to the whistleblower allegations from within the United States. (*See* Zach Decl. Ex. A.)

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I found that this court has personal jurisdiction over Santangelo with respect to the federal statutory claims and that the state claims are pendant in nature, i.e., that both state and federal claims arise from a common nucleus of operative facts, it follows this court has pendent jurisdiction over those claims and personal jurisdiction over Santangelo with respect to them.”)

<sup>10</sup> To the extent the Court finds that GSK PLC is not subject to general jurisdiction, and there is any doubt about the extent to which GSK PLC acted within the United States with respect to the claims, Plaintiffs are entitled to discovery to establish those minimum contacts. *Metcalfe v. Renaissance Marine, Inc.*, 566 F.3d 324, 336 (3d Cir. 2009) (stating that if “the plaintiff’s claim is not clearly frivolous [as to the basis for personal jurisdiction], the district court should ordinarily allow discovery on jurisdiction in order to aid the plaintiff in discharging that burden” “particularly . . . where the defendant is a corporation.”).

- GSK employees directed communications to Humphrey while he was located in the United States. (Compl. ¶ 80.)
- Witty and others falsely claimed, and publicly broadcast so as to reach U.S. regulators, that GSK had conducted an internal four month internal-investigation into the matter and found nothing amiss, (Compl. ¶ 109.)
- Ultimately, GSK PLC was fined and sanctioned by regulators in the United States for its participation in the scheme that led to Plaintiffs' injury. (Compl. ¶ 116.)

These facts establish that this Court has personal jurisdiction over GSK PLC for the claims asserted in the Complaint, which “arise out of” and/or “relate to” the foregoing contacts of GSK PLC with the United States. *See In re Automotive Refinishing Paint*, 229 F.R.D. 482, 487 (E.D. Pa. 2005.) Moreover, as referenced above, GSK PLC has already acknowledged that it is subject to personal jurisdiction in the United States in connection with the bribery scheme alleged in the Complaint. On September 30, 2016, GSK PLC itself “agreed to pay \$20 million to settle charges [with the SEC] that it violated the Foreign Corrupt Practices Act (FCPA) when its China-based subsidiaries engaged in pay-to-prescribe schemes to increase sales.” (Risk Decl. Ex. 7.) In addition to paying the fine, GSK PLC also agreed to a remediation process whereby it must report to the SEC over a two-year period on how it intends to implement improved anti-corruption compliance measures. (*Id.*)

This SEC enforcement proceeding, and the attendant Remedial Sanctions and Cease and Desist Order (Risk Decl. Ex. 8), directly relate to the allegations in the Complaint. Among other things, the factual findings that were made as part of the enforcement action by the SEC include:

- “Between at least 2010 and June 2013, employees and agents of GSK [PLC]’s China-based subsidiary and a China-based joint-venture engaged in various transactions and schemes to provide things of value to foreign officials, including healthcare professionals (“HCPs”), in order to improperly influence them and increase sales of GSK [PLC] products in China.” (*Id.* at 2);
- “The corrupt payments took varied forms, including gifts, improper travel and entertainment with no or little educational purpose, shopping excursions, family

and home visits, and cash. The costs associated with these payments were recorded in GSK [PLC]'s books and records as legitimate expenses, such as medical association sponsorships, employee expenses, conferences, speaker fees, and marketing costs.” (*Id.* at 3);

- “The funds used for the improper inducements were frequently obtained under the guise of, and falsely recorded in GSK [PLC]'s books and records as, legitimate travel and entertainment expense, marketing expense, speaker payments, medical associations payments, and promotion expense. Throughout this period GSK [PLC] failed to devise and maintain a sufficient system of internal accounting controls and lacked an effective anticorruption compliance program.” (*Id.* at 2); and
- The deficiencies in GSK [PLC]'s internal accounting controls and compliance program also led to instances of similar improper conduct in connection with sales in other countries in which GSK [PLC] operates. (*Id.*)

Accordingly, GSK PLC is subject to general and specific jurisdiction.

### **III. EACH OF PLAINTIFFS' CLAIMS IS ADEQUATELY PLEADED**

On a motion to dismiss, “the court is ‘required to accept as true all allegations in the complaint and all reasonable inferences that can be drawn from them after construing them in the light most favorable to the nonmovant.’” *Hartig Drug Co. Inc. v. Senju Pharm. Co.*, 836 F.3d 261, 268 (3d Cir. 2016) (citation omitted). The standard “simply calls for [plaintiffs to allege] enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary elements of the claim.” *Hollander v. Ranbaxy Labs. Inc.*, No. 10-793, 2011 WL 248449, at \*2 (E.D. Pa. Jan. 24, 2011). Defendants bear the burden of demonstrating dismissal is proper. *Narducci v. Timoney*, No. CIV A 99-CV-3933, 1999 WL 961221, at \*5 (E.D. Pa. Oct. 15, 1999). “[D]ismissal is appropriate only if it appears beyond a doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” *Oatess v. Sobolevitch*, 914 F.2d 428, 431 n.8 (3d Cir. 1990); *see also Johnson v. Hill*, 910 F. Supp. 218, 220 (E.D. Pa. 1996) (“A complaint is properly dismissed only if it appears that the plaintiff cannot prove any set of facts in support of its claim which would entitle it to relief.”)

### **A. The Complaint States a Claim for RICO and RICO Conspiracy**

In their motion, Defendants raise three arguments that the Complaint fails to state a claim under the applicable RICO statutes. At the outset, it is important to keep in mind that the Supreme Court has explained that “RICO is to be read broadly. This is the lesson not only of Congress' self-consciously expansive language and overall approach, but also of its express admonition that RICO is to ‘be liberally construed to effectuate its remedial purposes.’ The statute’s ‘remedial purposes’ are nowhere more evident than in the provision of a private action for those injured by racketeering activity.” *Sedima, S.P.R.L. v. Imrex Co., Inc.*, 473 U.S. 479, 497-498 (1985) (internal citations omitted). For the reasons set forth below, each of those arguments should be rejected.

#### **1. Plaintiffs Pled Facts Demonstrating Defendants’ Violations of Section 1962 Caused Their Damages**

Defendants’ contention that they are not liable to Plaintiffs for violations of Section 1962 because the Chinese authorities, not Defendants, injured Plaintiffs is wrong. *Hemi Group, LLC v. City of New York*, 559 U.S. 1 (2010), on which Defendants rely (Br. at 30), does not stand for the proposition for which Defendants cite it and does not bar Plaintiffs’ claim. *Hemi* “is about the RICO liability of a company for lost taxes it had no obligation to collect, remit, or pay, which harmed a party to whom it owed no duty.” *Id.* at 17. In that case, the City of New York alleged that Hemi, an online cigarette sales company, committed fraud by “selling cigarettes to city residents and failing to submit the required customer information to the State [of New York].” *Id.* at 2. However, “[n]either [New York] state nor city law require[d] Hemi to charge, collect or remit tax.” *Id.* at 4. Rather, the tax payment requirement fell to the purchasers who, the Court noted, “seldom pay it on their own.” *Id.* While there was a separate federal law that required “out-of-state vendors such as Hemi to submit customer information to the States into which they

ship cigarettes,” New York State was not obligated to share that information with New York City. *Id.* The Court therefore found the City’s causation theory to be too indirect because it was a situation in which the “defendant’s fraud on the third party (the State) has made it easier for a fourth party (the taxpayer) to cause harm to the plaintiff (the City).” *Id.* at 11. The Court also emphasized that the “the fourth-party taxpayers [] only caused harm to the City in the first place if they decided not to pay taxes they were legally obligated to pay.” *Id.* This does not mean, as Defendants contend, that the mere involvement of a third party will always preclude a RICO claim. As the court in *Hemi* held, there must be “*some* direct relation between the injury asserted and the injurious conduct alleged” that is neither “‘too remote,’ ‘purely contingent,’ or ‘indirect.’” *Id.* at 9 (quoting *Holmes v. Sec. Investor Protection Corp.*, 112 S. Ct. 1311 (1992)) (emphasis added).

In sharp contrast to *Hemi*, in which the defendants did not direct any conduct toward the plaintiff, here it is alleged that as part of its overarching scheme, Defendants lied directly to the *Plaintiffs*. That deception directly caused the damages in this case.

Notably, Defendants studiously avoid citing the leading Third Circuit case on this issue, presumably because it directly rejects the “presence of intermediaries” argument Defendants make here. In *In re Avandia Marketing, Sales Practices & Product Liability Litigation*, 804 F.3d 633 (3d Cir. 2015), the Third Circuit found that plaintiffs had sufficiently pled proximate causation and other facts against GSK (who was the defendant in that case) and upheld the denial of the district court’s motion to dismiss. In the *Avandia* case, like here, GSK argued “that the presence of intermediaries . . . destroys proximate causation.” 803 F.3d at 645. But the court rejected that argument and found, instead, that plaintiffs were “the ‘primary and intended victims

of the scheme to defraud’ and their injury was a ‘foreseeable and natural consequence of [the] scheme.’” (*Id.* (citing *Bridge v. Phoenix Bond & Indemnity Co.*, 128 S. Ct. 2131 (2008))).

As set forth above, there is no question that Plaintiffs were among the intended victims of Defendants’ fraud and that the injury was a foreseeable and natural consequence of GSK’s deception. GSK lied to Plaintiffs about the fact that they had previously investigated the whistleblower’s allegations and determined that they were unfounded (GSK knew they were true). (Compl. ¶¶ 52-53; 151-155.) Defendants further lied to Plaintiffs by claiming that GSK was the victim of an extortion plot by the whistleblower that was exposing their business and employees to criminal and regulatory sanction. (*Id.* ¶¶ 63; 152-153.)

*Avandia* also distinguished the line of cases that GSK relies on in its papers: “The Court in *Holmes*, *Anza*, and *Hemi* was concerned that the conduct causing plaintiffs’ injuries was different than the conduct allegedly constituting a RICO violation. Each of those cases featured plaintiffs alleging harm that was derivative of harm suffered by a more immediate victim of the RICO activity.” 804 F.3d at 643-44. Here, like in *Avandia*, the harm claimed by Plaintiffs is not derivative of harm suffered by anyone else.

## **2. Plaintiffs Have Alleged a Pattern of RICO Activity**

Defendants make the conclusory argument that the racketeering conduct alleged in the Complaint is “entirely unrelated” and “disjointed”. (Br. at 32.) The fact that Defendants do not even attempt to seriously address the allegations and predicate acts alleged in the Complaint is proof enough that this argument fails.

As set forth above in the Factual Background, Plaintiffs’ pattern could not be more clear. GSK operated a worldwide bribery and promotion scheme whereby it illegally made payments to doctors, hospitals and others in an effort to wrongfully bolster the sales of its drugs, then, after a settlement with the DOJ relating to part of this scheme (that carved out ongoing investigations as

to conduct outside the United States), Defendants sought to suppress evidence of conduct in China, and sought to make Plaintiffs unwitting participants in that effort. (See Factual Background at 7-9). Defendants then settled with the SEC relating to the conduct in China the evidence of which they had sought to suppress. (*Id.*). Defendants' argument that what they call the "three subsets of conduct within the purported enterprise," (Br. at 32) are unrelated and disjointed is therefore perplexing.

### **3. Plaintiffs Have Sufficiently Pled an Agreement**

Defendants argue that Plaintiffs' Second Cause of Action for RICO conspiracy should be dismissed because the Complaint fails to plead an agreement. In particular, Defendants argue, pointing to two paragraphs in the Complaint, that Plaintiffs offer only conclusory allegations with respect to the Defendants' participation in the whistleblower investigation. (Br. at 34.) The argument is easily rejected because, as a matter of law, it misunderstands the nature of the requisite agreement under Section 1962(d). To state a claim, a plaintiff must allege a knowing agreement "to facilitate a scheme which includes the operation or management of a RICO enterprise." *Smith v. Berg*, 247 F.3d 532, 538 (3d Cir. 2001). However, the agreement need not relate to participation in any particular predicate act or specific instance of conduct. Rather, "one who opts into or participates in a conspiracy is liable for the acts of his co-conspirators which violate section 1962(c) even if the defendant did not personally agree to do, or to conspire with respect to, any particular element." *Id.* at 573.<sup>11</sup> The Complaint alleges numerous facts relating to Defendants' agreement to engage in the bribery and promotion scheme—that is, the RICO

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<sup>11</sup> As the Third Circuit further explained: "A conspirator must intend to further an endeavor which, if completed, would satisfy all of the elements of a substantive criminal offense, but it suffices that he adopt the goal of furthering or facilitating the criminal endeavor. He may do so in any number of ways short of agreeing to undertake all of the acts necessary for the crime's completion. One can be a conspirator by agreeing to facilitate only some of the acts leading to the substantive offense. *Id.* at 537 n.9."

enterprise—to meet that pleading burden. And, in any event, although they need not do so to satisfy the “agreement” requirement, Plaintiffs do plead facts that demonstrate Defendants actively participated in the suppression of the whistleblower’s allegations. This includes the acts of Defendants’ employees based in Asia as well as those based in the U.S. and U.K.<sup>12</sup>

#### **4. Plaintiffs Have Sufficiently Pled a Domestic Injury**

Defendants argue that Plaintiffs do not have standing to bring a RICO claim because the Complaint does not plead a “domestic injury” pursuant to the Supreme Court’s recent decision in *RJR Nabisco, Inc. v. European Cmty*, 136 S. Ct. 2090 (2016). That is wrong. As an initial matter, the Supreme Court was clear in *RJR Nabisco* that what constitutes a “domestic injury” in “any given case will not always be self-evident, as disputes may arise as to whether a particular alleged injury is ‘foreign’ or ‘domestic.’” *Id.* at 2111. In that case, there was no “domestic injury” because plaintiff’s case “rest[ed] entirely on injury suffered abroad” and the Court declined to further define the meaning of “domestic injury,” leaving it to subsequent cases to develop the test. *Id.* Since then, a few district courts throughout the country have interpreted what “domestic injury” means and attempted to articulate guiding principles to address this fact specific issue. As discussed below, Defendants cherry-pick among these decisions, relying on a distinguishable outlier case, and failing to address the contrary authority. None of the cases Defendants cite suggest that Plaintiffs have not alleged a domestic injury sufficient to give them RICO standing on the facts pled in this case.

As alleged in the Complaint, Plaintiffs operated an investigative services firm whose primary function was to advise and consult with U.S. corporations and law firms on FCPA

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<sup>12</sup> In a footnote (Br. at 35 n.9), Defendants note that a number of courts in this circuit have held that corporations cannot engage in a RICO conspiracy solely with its own subsidiaries and employees. Presumably Plaintiffs do not advance this argument as a basis for dismissal because, among other reasons, the Complaint alleges numerous other, non-GSK co-conspirators. (Compl. ¶ 123.)

investigations and other U.S. regulatory matters. Most of the firm's revenue was generated from the United States in connection with the numerous ongoing engagements it has with American law firms and businesses. All of that revenue was lost when the Defendants' racketeering conduct destroyed Plaintiffs' business.

Defendants rely principally on *Bascuñan v. ELS*, 2016 WL 5475998 (S.D.N.Y. Sept. 28, 2016). The holding of this case has been criticized or rejected by many of the other courts analyzing these issues even within the same district. *See, e.g., City of Almaty, Khazakhstan v. Ablyazov*, 15-CV-5345 (AJN), 2016 WL 7756629, at \*8 (S.D.N.Y. Dec. 23, 2016) (noting that "[t]he *Bascuñan* approach has garnered somewhat mixed reception among the few other courts to address the domestic-injury issue" and declining "endorse an absolutist version of the rule"); *Tatung Co., Ltd. v. Shu Tze Hsu*, SA CV 13-1743 (DOC), 2016 WL 6683201, at \*6 (C.D. Cal. Nov. 14 2016) (declaring "this Court declines to follow *Bascuñan*" and providing criticism of the decision). Defendants ignore those decisions.

Defendants also ignore *Elsevier Inc. v. Grossmann*, 12 Civ. 5121 (KPF), 2016 WL 7077109 (S.D.N.Y. Aug. 4, 2016), in which the court "conclude[d] that, in the RICO context, courts should employ a more flexible inquiry to determine where an injury occurs . . . [and that] [i]f the plaintiff has suffered an injury to his or her business, the court should ask where *substantial negative business consequences occurred*." *Id.* at \*13 (emphasis added). The *Elsevier* court found no "domestic injury" because the sales and customers of the plaintiff's business were all located abroad in Brazil. *Id.* By contrast, in this case, Plaintiffs' investigative services business lost its U.S.-based revenue, clients and ongoing and prospective contracts when Defendants racketeering conduct destroyed the business. (Compl. ¶¶ 3, 5, 9.) It is also worth noting that the work for which Defendants hired Plaintiffs, which caused Plaintiffs harm, was

related directly to Defendants response to ongoing regulatory inquiries by the DOJ and SEC in the United States. Moreover, those injuries to Plaintiffs business distinguish this case from *Bascuñan*, which related to loss of property, namely being defrauded out of \$64 million. *Bascuñan*, 2016 WL 5475998, at \*6; *see Elsevier*, 2016 WL 7077109 at \*13 (comparing business injuries to property injuries and noting that “[b]y contrast [to business injuries], if the plaintiff has suffered an injury to his or her property, the court should ask where the plaintiff parted with the property or where the property was damaged.”).

Defendants also ignore *Akishev v. Kapustin*, No. 13-7152 (NLH), 2016 WL 7165714 (D.N.J. 2016), the only case to come out of this Circuit, in which the court implicitly rejected *Bascuñan*, stating that the domestic injury requirement ““does not mean that foreign plaintiffs may not sue under RICO.”” *Id.* at \*7 and n.9 (quoting *RJR Nabisco*, 136 S. Ct. at 2110 n.2). Instead, the *Akishev* court looked to *how* the plaintiffs suffered their injury and concluded that that United States-based schemes targeting foreign plaintiffs cause domestic injuries. *Id.* at \*7-\*8. In particular, the court noted that “[a] person responsible for a United States-based fraudulent scheme to defraud people overseas should not escape liability under a federal law that permits private causes of action to redress that fraud simply because the scheme targets foreign citizens over the internet.” The court went on to conclude that:

In a fraudulent and criminal scheme that crosses borders, the extraterritoriality analysis should be a two-way street. The Plaintiffs here could have been anywhere in the world and actually came from several countries. Defendants, however, choose to operate their fraudulent scheme from New Jersey and Pennsylvania. The locus delicti of the crimes committed is the United States. Nothing in 18 U.S.C. § 1964(c) suggests Congress intended to exclude a scenario like this one from the reach of a private victim, even a foreign one.

*Id.* at \*8. Other cases have found similar guiding principles in assessing what constitutes a “domestic injury. *See, e.g., Tatung Co. Ltd.*, 2016 WL 6683201, at \*7 (adopting an approach

similar to the *Akishev* court’s test and noting that “[i]t is ludicrous to think that a foreign individual could not sue under civil RICO for financial injuries incurred while they are working, traveling, or doing business in this country as the result of an American RICO operation. But, this is the logical application of the *Bascuñan* rule.). Here again, Defendants coordinated and operated their fraudulent scheme to evade U.S. regulatory sanctions from this forum and targeted Plaintiffs as unwitting instruments to achieve that goal.

*Union Commercial Services Ltd. v. FCA Int’l Operations LLC*, No. 16-cv-10925, 2016 WL 6650399 (E.D. Mich. Nov. 10, 2016), a case Defendants do cite, actually supports a finding of domestic injury here. In that case the court adopted an antitrust-type approach to defining “domestic injury.” Under that test, the court must determine whether there is a “domestic injury” “by assessing whether a defendant’s conduct is intended to or has produced ‘substantial effects’ in the United States.” *Id.* at \*4. The *Union Commercial* court found that plaintiff suffered no domestic injury because the entirety of the specific injury alleged, “lost sales and lost profits,” occurred outside of the United States. *Id.* at \*5. In this case, Plaintiffs allege conduct that demonstrates a domestic injury under the *Union Commercial* standard because Plaintiffs’ lost revenue, clients, and ongoing and prospective engagements in the United States. Those injuries and Defendants’ other conduct therefore suffice to establish a “domestic injury” under this test as well.

In sum, the Supreme Court left open the question of what constitutes a “domestic injury.” But, as set forth above, district courts across the country have worked to formulate a test to fill the gap. Plaintiffs, who operated a U.S. facing business and lost substantial U.S. revenue as a result of Defendants’ conduct, have pleaded facts sufficient to meet the applicable standards that have been articulated and demonstrated a “domestic injury” in this case.

## **B. Plaintiffs' State Law Claims Are Adequately Pleaded**

### **1. The Court Has Diversity Jurisdiction, And In Any Event Can Exercise Supplemental Jurisdiction Over Plaintiffs' State Law Claims**

As an initial matter, Defendants' argument that the Court cannot exercise diversity jurisdiction and that it therefore lacks subject matter jurisdiction over Plaintiffs' state law claims is both wrong and irrelevant. The basis of Defendants' argument is the wholly unsupported assertion that Plaintiff Yu is "not domiciled in the U.S." (Br. at 26.) The Complaint alleges that Yu is an American citizen (Compl. ¶ 7), and there is no basis for Defendants' assertion that she is not domiciled in the U.S. In any event, the Court has supplemental jurisdiction over Plaintiffs' state law claims under 28 U.S.C. § 1367, which provides that where the district court has original jurisdiction – which Defendants do not contest – it also has "supplemental jurisdiction over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution." Defendants do not argue, nor could they, that Plaintiffs' state law claims do not form part of the same case and controversy as the Federal claims.

### **2. Plaintiffs Have Adequately Stated A Claim for Fraud**

Defendants' only argument is that the fraud claim fails because "the wrong defendants once again were named," citing *Davis v. Wells Fargo U.S. Bank Nat'l Ass'n*, No. 14-07014, 2015 WL 3555301, at \*1 (E.D. Pa. June 8, 2015). (Br. at 35.) In that case, the district court granted the insurance holding company defendant's motion to dismiss a "forced insurance" claim under Rule 12(b)(1) for lack of subject matter jurisdiction, relying on declarations by the defendants that asserted, like Defendants here, that the defendant was merely a holding company with the sole purpose of holding other companies and that it did not issue insurance. *Davis*, 2015 WL 3555301 at \*1, 3-4; *compare to* "Declaration of GlaxoSmithKline PLC," Exhibit 13 to Risk

Declaration. What Defendants fail to note is that the holding of the district court in *Davis* on which they rely was vacated by the Court of Appeals. *Davis v. Wells Fargo*, 824 F.3d 333, 346-350 (3d Cir. 2016). The Court of Appeals held that the district court was wrong to treat the defense – the same one asserted by Defendants here – “the wrong defendants were named” – as a motion to dismiss under 12(b)(1) and, crucially, was wrong to allow the defendants to rely on declarations, like those submitted here, disclaiming involvement. *Id.* As the Court of Appeals reasoned, Defendants’ argument, if accepted, “would allow any litigant whose defense is ‘you’ve got the wrong party’ to frame that lack-of-responsibility defense not as a merits challenge to be tried or to be considered under Rule 12(b)(6) or the summary judgment provisions of Rule 56 but as a Rule 12(b)(1) standing challenge, thereby empowering the defendant to buttress its legal arguments with factual assertions that contradict those in the complaint.” *Id.* at 348. The Court further held that, applying the proper standard on a motion to dismiss under Rule 12(b)(6), *i.e.*, taking the allegations of the complaint as true, the plaintiff had stated a claim against the holding company. In doing so, it expressly rejected the defendant’s argument that the plaintiff should have named its subsidiary as a defendant, noting that the defendant and its subsidiary “are related entities and the extent of their intertwined operations is a matter that has not yet been tested by the adversary process.” *Id.* at 347.

Here as in *Davis*, Defendants contend that Plaintiffs should have named another party and that Defendants themselves did nothing wrong. But as the Court of Appeals held, defendant

argues that [the plaintiff] has filed suit against the wrong party, that his claims against [defendant] are actually without merit because [defendant] has done nothing wrong. That may be true, and, if so, the ordinary course of litigation will root it out. But [defendant] may not short-circuit the usual process, flip the burden of persuasion, and permit itself to submit competing facts to support its argument.

*Id.* at 349.

The gravamen of the Complaint is that the Defendants, concerned about exposure to liability outside of China, including in the United States for violations of the FCPA, sought to cover up evidence of corruption in China and silence a whistleblower, and the Complaint plausibly alleges that the Defendants engaged in the alleged fraudulent conduct through their agents based in China (regardless of which entity technically employed those agents).

Defendants are free to try to establish at a subsequent phase of this litigation that the individuals named in the Complaint who interacted with Plaintiffs, including Mark Reilly and Brian Cahill, were operating entirely independently of Defendants, including managers in the U.S. and U.K. to whom they presumably reported (as implausible as that sounds). However, at the pleading stage, Defendants may not rely on declarations indicating that those individuals were not “employed by GSK PLC during the relevant time period” (“Declaration of GlaxoSmithKline PLC,” Exhibit 13 to Risk Declaration). *See Davis*, 824 F.3d at 351 (holding the court “must ignore” defendant’s declarations when ruling on the 12(b)(6) motion). Defendants offer no other basis for dismissal of the fraud claim, and its motion to dismiss for failure to state a claim must therefore be denied.

### **3. Plaintiffs Have Adequately Stated A Claim for Civil Conspiracy**

As Defendants acknowledge, the elements of civil conspiracy are (1) a combination of two or more persons acting with a common purpose to do an unlawful act or to do a lawful act by unlawful means or for an unlawful purpose; (2) an overt act done in pursuance of the common purpose; and (3) actual legal damage. (Br. at 36, citing *Morilus v. Countrywide Home Loans, Inc.*, 651 F. Supp. 2d. 292, 312 (E.D. Pa. 2008).) Defendants do not contest that Plaintiffs have alleged those elements. Rather, they argue that the civil conspiracy claim fails because the Complaint does not plausibly allege that Defendants acted with personal malice toward the Plaintiffs. (*Id.*) That argument rests on a fundamental misreading of the law. As an initial

matter, in the decision on which Defendants rely, the issue before the district court was not whether a claim for civil conspiracy had been stated, but whether there was sufficient evidence of civil conspiracy to commit fraud to survive summary judgment. To the extent the district court's decision implied that a plaintiff must allege an additional element to this state law claim – *i.e.*, actual malice toward the plaintiff – where the plaintiff alleges an *unlawful* act, like here, as opposed a *lawful* act for an unlawful purpose, that implication is inconsistent with the law of Pennsylvania. Pennsylvania courts have held that a defendant is not liable for civil conspiracy if it engages in *otherwise lawful* conduct unless the defendant's objective is to harm the plaintiff rather than advance its own interests. *See e.g. Thompson Coal Co. v. Pike Coal Co.*, 412 A.2d 466, 473 (Pa. 1979). That is simply another formulation of the second of the two predicates for a civil conspiracy claim – *i.e.*, “a lawful act by unlawful means or for an unlawful purpose.” These decisions merely embody the uncontroversial concept that: “[t]he mere fact that two or more persons, *each with the right to do a thing*, happen to do that thing at the same time is not by itself an actionable conspiracy.” *Thompson Coal Co. v. Pike Coal Co.*, 412 A.2d 466, 473 (Pa. 1979) (holding that defendant was not liable for civil conspiracy based on otherwise lawful conduct absent a showing that the conduct was intended to harm the plaintiff) (emphasis added) (quoting *Fife v. Great Atl. and Pac. Tea Co.*, 52 A.2d 24, 39 (Pa.1947)). Here, by contrast, it is alleged that Defendants acted with a common purpose to do an *unlawful act*, not to do a lawful act by unlawful means or for an unlawful purpose. The question of intent to harm the plaintiff is therefore irrelevant.

#### **4. Plaintiffs Adequately Alleged Severe Emotional Distress**

Only by willfully ignoring the Complaint are Defendants able to glibly assert, as they do, that Plaintiffs' claims of severe emotional distress are “threadbare legal conclusions.” (Br. at 37.) The Complaint sets out in sometimes painful detail the suffering, both emotional and

physical, that Plaintiffs underwent during their nightmarish arrest, summary conviction, and brutal imprisonment. These allegations more than satisfy any standard for a claim of severe emotional distress.

Nor is there any merit to Defendants' argument that the causal link between Defendants' conduct and Plaintiffs' suffering is broken by the "independent" acts of the Chinese authorities. (Br. at 37-38.) Numerous cases have held that a plaintiff may seek damages for emotional distress against a defendant whose negligence resulted in plaintiff's imprisonment, even though the actions of others proximately brought about the imprisonment. *See, e.g., Lawson v. Nugent*, 702 F. Supp. 91 (D. N.J. 1988) (holding that client alleging legal malpractice could recover damages for emotional distress attributable to extra 20 months of confinement in maximum security penitentiary which were allegedly due to negligent representation); *Bowman v. Doherty*, 686 P.2d 112, 119 (Kan. 1984) (holding that "the act of the attorney which led to the injury suffered by his client was the failure of the attorney to act, which caused the client to be placed in jail and deprived of his freedom. One being negligently deprived of his freedom suffers an injury which could cause mental distress."); *Wagenmann v. Adams*, 829 F.2d 196, 222 (1st Cir.1987) (holding that "an attorney who commits malpractice is liable to his client for any reasonably foreseeable loss caused by his negligence including emotional distress resulting from the loss of liberty.").

#### **5. Plaintiffs' State Law Claims Are Not Barred By the Statute of Limitations**

As an initial matter, Defendants are wrong when they assert that Plaintiffs' claims accrued between April and July 2013 when Defendants committed fraud. (Br. at 42.) It is beyond question that a claim for fraud does not accrue, until, at the earliest, the plaintiff becomes aware, or should have become aware through the exercise of ordinary diligence, that he was

defrauded. *Beauty Time, Inc. v. VU Skin Systems, Inc.*, 118 F.3d 140, 144 (3d Cir. 1997) (“It is well-established that Pennsylvania law recognizes an exception to the statute of limitations which ‘delays the running of the statute until the plaintiff knew, or through the exercise of reasonable diligence should have known, of the injury and its cause.’”); *see also Merck & Co., Inc. v. Reynolds*, 559 U.S. 633 (2010) (explaining history and underpinnings of the “discovery rule” applicable to fraud claims and holding “[t]his court long ago recognized that something different was needed in the case of fraud, where a defendant’s deceptive conduct may prevent a plaintiff from even knowing that he or she has been defrauded. Otherwise, ‘the law which was designed to prevent fraud’ could become ‘the means by which it is made successful and secure.’”). Moreover, because the question of when the plaintiff became or should have become aware of the claim is highly fact-intensive, it is generally inappropriate for resolution on a motion to dismiss. *Schmidt v. Skolas*, 770 F.3d 241, 251 (3d Cir. 2014) (“Only where the facts are so clear that reasonable minds cannot differ may the commencement of the limitations period be determined as a matter of law.”) (internal quotation marks and citations omitted). In addition, because failure to timely file is an affirmative defense, the plaintiff need not plead compliance with the statute of limitations. *Id.* Only where the complaint itself demonstrates unequivocally that the claim is not timely can the issue be resolved on a motion to dismiss. *Id.*

Here, the Complaint does not identify when Plaintiffs learned that they had been defrauded, and the court therefore cannot grant Defendants’ motion based on the statute of limitations. *Id.* If anything, the Complaint indicates that Plaintiffs’ fraud claim accrued, *at the earliest*, on September 19, 2014, when Defendants admitted for the first time that they had engaged in bribery, at which point Plaintiffs could have learned for the first time that they had been lied to. (Compl.¶ 116.)

However, even taking the earliest date, GSK's public admission of guilt on September 19, 2014, the Plaintiffs' claims are timely. The parties entered into a 60-day tolling agreement effective as of September 12, 2016. Accounting for the tolling agreement, Plaintiffs' Complaint was filed on November 15, 2016, one year, eleven months, and 26 days after Defendants' admission of guilt. The statute of limitations for fraud in Pennsylvania is two years. Accordingly, Plaintiffs' fraud claim is timely even if it accrued on September 19, 2014.

Defendants' motion to dismiss Plaintiffs' claims for intentional and negligent infliction of emotional distress based on the statute of limitations fails for similar reasons. Although Plaintiffs Humphrey and Yu began to suffer injury on July 10, 2013 when they were detained by police in China, they did not have a basis to assert their claims, which require, respectively, a showing of negligence and intent, until, at the earliest, when Defendants admitted their guilt on September 19, 2014, and in reality much later in light of the fact that when Defendants admitted their wrongdoing, Humphrey and Yu were already being held in a Chinese prison with no access to information. In addition, Plaintiffs Humphrey and Yu's claims of infliction of emotional distress are based on their incarceration, which continued until at least June 9, 2015. Based on that and the fact that they were unable to discover the basis for their claims until after they were released, their claims for intentional and negligent infliction of emotional distress accrued on or after June 9, 2015. However, as discussed above, under the applicable two-year statute of limitations, Plaintiffs' claims were timely even if they accrued on the earlier date of September 19, 2014, taking into account the 60-day tolling agreement between the parties. To the extent there is any doubt about when Plaintiffs' claims accrued, Defendants' motion must be denied. *See Schmidt v.*, 770 F.3d 241.

Regardless of the calculations above, Plaintiffs' state law claims are timely because, pursuant to the doctrine of equitable tolling, the statute of limitations for their claims did not run while Humphrey and Yu were imprisoned in China. Equitable tolling applies, among other circumstances, "where the plaintiff in some extraordinary way has been prevented from asserting his or her rights." *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1387 (3d Cir. 1994.) The application of the doctrine is fact intensive and inappropriate for resolution on a motion to dismiss under Rule 12(b)(6). *Id.* at 1389 (holding that the question of whether equitable tolling applies required a factual inquiry into defendant's conduct). Among other things, it will need to be determined to what extent Plaintiffs Humphrey and Yu were able to assert their claims while they were in prison, bearing in mind that this was not a prison in the United States, where prisoners have rights, but a prison in one of the most repressive dictatorships in the world, where prisoners have no rights.

**C. The Complaint Should Not Be Dismissed for Failure to Join An Indispensable Party**

**1. GSK China is Not a Necessary Party Under Rule 19(a)**

GSK argues that GSK China is a necessary party under Federal Rule of Civil Procedure 19(a). Once again, GSK's argument is based on a deliberate mischaracterization of the allegations in the Complaint. The allegations of the Complaint are directed at the Defendants, not GSK China. As alleged in the Complaint, GSK's global senior executives received whistleblower accusations of widespread corruption in China at a time when GSK was dealing with investigations into its global practices by authorities in the United States and United Kingdom. For example, the Complaint alleges that GSK's global CEO Andrew Witty, its Global Head of Compliance, and its Global General Counsel Dan Troy received an anonymous email, attaching the Mark Reilly sex tape, that triggered Plaintiffs' involvement. (Compl. ¶¶ 54-55.)

The Complaint further alleges that “on January 16, 2013, approximately six months after GSK’s settlement with the DOJ, an anonymous whistleblower sent an email entitled “Notification of Bribery by GSK in China” to GSK’s Audit Committee, Board of Directors, Executive Management, including CEO Sir Andrew Witty.” (*Id.* at 30.) The Complaint also alleges that “on May 10, 2013, GSK Audit Chair Judy Lewent and other recipients received another email from the same anonymous email address as the January 10 whistleblower email.” (*Id.* at ¶ 67.)

The Complaint alleges that as a result of these whistleblower allegations – sent to Defendants at the highest levels – Defendants, through their agents in China, induced Plaintiffs to engage in a fraudulent investigation designed to silence a whistleblower and cover up a bribery scheme that Defendants did not want to come to light given the ongoing investigations by U.S. and U.K. authorities. (*Id.* at ¶¶ 49-63.) Again, Defendants remain free at a later stage to try to prove that Mark Reilly, Brian Cahill and the other individuals who interacted directly with Plaintiffs were acting completely independently of their superiors Andrew Witty, Dan Troy, and others. But at the motion to dismiss phase, the allegations of the Complaint must be taken as true.

Accordingly, this is not a case where liability is asserted solely in a vicarious capacity based on a parent company being vicariously liable for the acts of its subsidiary as was the case in *Carl Schroeter GmbH v. Crawford & Co.*, No. 09-946, 2009 WL 1408100 (E.D. Pa. May 19, 2009), cited by Defendants. (Br. at 40) (dismissing without prejudice and holding that subsidiary would be a necessary party where there were no allegations concerning the corporate grandparent defendant and the only basis for liability against the corporate grandparent was vicarious liability for the conduct of the subsidiary, and allowing plaintiffs to replead to allege a

factual basis for asserting liability over corporate grandparent). The alleged wrongdoing here was by the Defendants.

In all events, Defendants have failed to establish that GSK China is a necessary party under Rule 19(a). Rule 19(a) provides:

A person ... must be joined as a party in the action if (1) in the person's absence complete relief cannot be accorded among those already parties; or (2) the person claims an interest relating to the subject of the action and is so situated that the disposition of the action in the person's absence may (i) as a practical matter impair or impede the person's ability to protect that interest; or (ii) leave any of the persons already parties subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by reason of the claimed interest.

"A Rule 19(a)(1) inquiry is limited to whether the district court can grant complete relief to the persons already parties to the action. The effect a decision may have on the absent party is not material." *Janney Montgomery Scott, Inc. v. Shepard Niles, Inc.*, 11 F.3d 399, 405 (3d Cir. 1993.) Defendants do not even attempt to show that complete relief cannot be granted in GSK China's absence.

GSK China has not asserted any interest such as would be required under Rule 19(a)(2). *See ConnTech Dev. Co. v. Univ. of Conn. Educ. Prop., Inc.*, 102 F.3d 677, 683 (2d Cir.1996) ("[i]t is the absent party that must 'claim an interest' for Rule 19(a)(2) purposes. [A party's] self-serving attempts to assert interests on behalf of [a third party] fall outside the language of Rule 19(a)(2).") But even Defendants do not claim that GSK China has an interest in this action, much less that it cannot protect that interest, or that any of the parties are at risk of multiple or inconsistent obligations based on such unidentified interest.

GSK China is, at most, a potential joint-tortfeasor or agent of the Defendants. The law is clear that joinder of such parties is permissive, not necessary under Rule 19(a). *Temple v. Synthes Corp., Ltd.*, 498 U.S. 5, 8 (1990) (holding surgeon and hospital as potential joint

tortfeasors not necessary parties to case against manufacturer of device implanted in plaintiff's spine); *Huber v. Taylor*, 532 F.3d 237, 249-250 (3d Cir. 2008) (holding local counsel as potential joint tortfeasor/agent not necessary party in legal malpractice case); *Orengo v. Berkel & Company Contractors, Inc.*, No. 16-4635, 2016 WL 7474476, at \*3 (E.D. Pa. Dec. 29, 2016) (holding employee driver not necessary party in negligent driving case against driver's employer, and collecting cases holding agents/principals not necessary parties). Defendants should not be permitted to use Rule 19 to make an "attempted end-run on the general rule that the plaintiff gets to decide who among alleged joint and several tortfeasors to sue." *Alpha Pro Tech, Inc. v. VWR Int'l. LLC*, 984 F. Supp. 2d 425, 459 (E.D. Pa. 2013).

Because Defendants have failed to establish that GSK China is a necessary party under Rule 19(a), the Court need not analyze whether dismissal is appropriate under Rule 19(b).

## **2. Dismissal Is Not Warranted Under Rule 19(b)**

Even if GSK China were a necessary party (and it is not), dismissal would not be appropriate under Rule 19(b). Under Rule 19(b), four factors, although not exhaustive, are "the most important considerations" in determining whether a party is indispensable:

first, to what extent a judgment rendered in the person's absence might be prejudicial to the person or those already parties; second, the extent to which, by protective provisions in the judgment, by the shaping of relief, or other measures, the prejudice can be lessened or avoided; third, whether a judgment rendered in the person's absence will be adequate; [and] fourth, whether the plaintiff will have an adequate remedy if the action is dismissed for nonjoinder.

*General Refractories Co. v. First State Ins. Co.*, 500 F.3d 306, 319 (3d Cir. 2007) (quoting Fed.R.Civ.P. 19(b) (internal quotation marks and citations omitted).

Defendants make no attempt to show that a judgment rendered in GSK China's absence would be prejudicial to anyone. Nor do they explain why a judgment rendered in GSK's absence would be inadequate. Importantly, the question under this factor is whether the judgment will be

adequate to *the plaintiff*. *Id.* Defendants have offered no reason to believe Plaintiffs would not be able to recover fully from the Defendants. Defendants' citation of the District of Delaware's opinion in *Jurimex Kommerz Transit G.m.b.H. v Case Corp.*, 201 F.R.D. 337, 340-341 (D. Del. 2001) is misplaced. In that case, the plaintiff sought to hold the parent company liable for the conduct of its subsidiaries. Here by contrast, as discussed above, the Complaint alleges that *Defendants*, not GSK China, received the whistleblower allegations and orchestrated a cover-up that led to the arrest and imprisonment of Plaintiffs in an attempt (futile, as it turned out) to avoid liability *themselves* in the U.S. Moreover, the Court of Appeals in *Jurimex* reversed the District of Delaware decision to the extent it failed to allow the plaintiff to amend its complaint to flesh out its theory of liability over the parent company, stating:

we can presume that the factual nature of the relationship alleged in the amended complaint would be better understood after discovery. For example, during its earlier request for discovery, Jurimex asked for all documents concerning the communications between Case and its subsidiaries specifically limited to the Golden Grain transaction. Evidence of control by Case over the actions of Case France, Paris, and Neustadt would likely be found in such documents and demonstrate agency.

*Jurimex Kommerz Transit G.M.B.H. v. Case Corp.*, 65 Fed.App'x. 803 (3d Cir. 2003). Here, of course, the Complaint already articulates the grounds for liability against Defendants. Similarly, in the only other authority cited by Defendants, *Carl Schroeter GmbH*, 2009 WL 1408100 (E.D. Pa. May 19, 2009) which is inapposite for the reasons discussed above, the court allowed plaintiffs to replead to allege a factual basis for asserting liability over corporate grandparent. *Id.* at \*12 ("Plaintiffs should, however, be entitled to amend their complaint").

Perhaps most significantly, Defendants are wrong when they assert that Plaintiffs would have an adequate remedy if the action is dismissed for non-joinder. As discussed above, Plaintiffs cannot enter China and therefore cannot prosecute their claims there. Particularly

where the other factors also do not support dismissal, the Court cannot, “in equity and good conscience,” dismiss this action on grounds of non-joinder. *Id.* at \*3.

### **CONCLUSION**

For the reasons set forth above, Plaintiffs respectfully request that Defendants’ Motion to Compel Arbitration, or, in the Alternative, to Dismiss the Complaint, be denied in its entirety.

Dated: Philadelphia, Pennsylvania  
March 3, 2017

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

Pursuant to Fed. R. Civ. P. 5(b)(2)(D) and the Local Rules of this Court, I hereby certify that the foregoing Memorandum in Opposition to Defendants' Motion to Compel Arbitration, or, in the Alternative, to Dismiss the Complaint was filed by ECF on March 3, 2017, is available for viewing and downloading from the ECF system, and has been served on all parties of record by ECF.

Dated: March 3, 2017  
New York, New York

/s/ John T. Zach  
John T. Zach

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

PETER HUMPHREY, YU YINGZENG, and  
CHINAWHYS COMPANY LTD.,

Plaintiffs,

v.

GLAXOSMITHKLINE PLC and  
GLAXOSMITHKLINE LLC,

Defendants.

No. 16 Civ. 5924 (NIQA)

**[PROPOSED] ORDER DENYING DEFENDANTS GLAXOSMITHKLINE PLC AND  
GLAXOSMITHKLINE LLC'S MOTION TO COMPEL ARBITRATION, OR, IN THE  
ALTERNATIVE, MOTION TO DISMISS THE COMPLAINT**

This Matter, having come before the Court on the Defendants' motion to compel arbitration and Defendants' motion to dismiss the complaint, and it appearing, upon argument of counsel and for good cause shown, that the Motion should be denied:

IT IS HEREBY ORDERED that Defendants' motion to compel arbitration and Defendants' motion to dismiss the complaint is denied.

Dated: \_\_\_\_\_

By: \_\_\_\_\_  
Hon. Nitza I. Quiñones Alejandro  
United States District Judge

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PETER HUMPHREY, YU YINGZENG, and  
CHINAWHYS COMPANY LTD.,

Plaintiffs,

v.

GLAXOSMITHKLINE PLC and  
GLAXOSMITHKLINE LLC,

Defendants.

No. 16 Civ. 5924 (NIQA)

**DECLARATION OF JOHN T. ZACH IN SUPPORT OF PLAINTIFFS'  
OPPOSITION TO DEFENDANTS GLAXOSMITHKLINE PLC AND  
GLAXOSMITHKLINE LLC'S MOTION TO COMPEL ARBITRATION, OR, IN THE  
ALTERNATIVE, MOTION TO DISMISS THE COMPLAINT**

JOHN T. ZACH, an attorney duly admitted to practice law *pro hac vice* in the U.S. District Court for the Eastern District of Pennsylvania, affirms, under penalty of perjury, the following to be true:

1. I am a partner in the law firm of Boies, Schiller & Flexner LLP, counsel for Plaintiffs Peter Humphrey, Yu Yingzeng, and ChinaWhys Company Ltd. (together, "Plaintiffs") in the above-captioned matter. I submit this Declaration in Support of Plaintiffs' Opposition to Defendants' motion to compel arbitration, or, in the alternative, Defendants' motion to dismiss.

2. Attached hereto as Exhibit A is a true and correct copy of an article published by the Association of Corporate Counsel on November 21, 2016 entitled "'Our most valuable commodity is our time': GSK's Dan Troy on Running a Global Legal Department," retrieved on February 28, 2017 from the following URL: <https://www.acc.com/clo/perspectives/copy-of-november-2016-clo-ebook>.

3. Attached hereto as Exhibit B is a true and correct copy of a page from Defendants'

website entitled “Headquarters,” retrieved on March 2 from the following URL:

<http://www.gsk.com/en-gb/contact-us/headquarters/>.

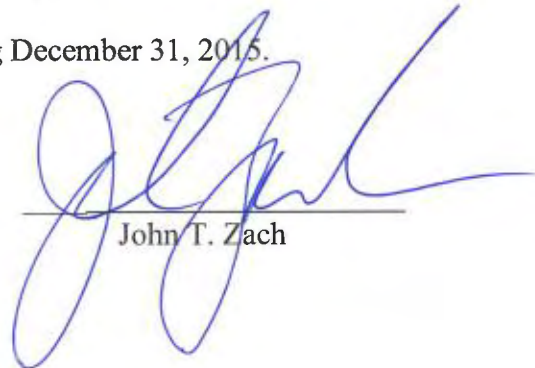
4. Attached hereto as Exhibit C is a true and correct copy of relevant excerpts from the Annual Report for the year ending December 31, 2015 for GlaxoSmithKline plc and its subsidiary undertakings.

5. Attached hereto as Exhibit D is a true and correct copy of the Declaration of Peter Humphrey, dated March 2, 2017, which is submitted exclusively in opposition to Defendants’ Motion to Compel Arbitration.

6. Attached hereto as Exhibit E is a true and correct copy of pages from Defendants’ website entitled “Global Compliance,” retrieved on March 2 from the following URLs <http://www.gsk.com/en-gb/about-us/governance/global-compliance/>; <http://www.gsk.com/en-gb/about-us/governance/global-compliance/overview/>.

7. Attached hereto as Exhibit F is a true and correct copy of relevant excerpts from GlaxoSmithKline Capital plc’s Annual Report for the year ending December 31, 2015.

Dated: March 3, 2017  
New York, New York



John T. Zach

**CERTIFICATE OF SERVICE**

Pursuant to Fed. R. Civ. P. 5(b)(2)(D) and the Local Rules of this Court, I hereby certify that the foregoing Declaration of John T. Zach in Opposition to Defendants' Motion to Compel Arbitration, or, in the Alternative, to Dismiss the Complaint (with exhibits) was filed by ECF on March 3, 2017, is available for viewing and downloading from the ECF system, and has been served on all parties of record by ECF.

Dated: March 3, 2017  
New York, New York

/s/ John T. Zach  
John T. Zach

## **Exhibit A**



Overview

Resources

Benchmarking

Why Join ACC?

NOVEMBER 21, 2016

**"OUR MOST VALUABLE COMMODITY IS OUR TIME:" GSK'S DAN TROY ON RUNNING A GLOBAL LEGAL DEPARTMENT**



Dan Troy is senior vice president and general counsel of GSK, a science-led global healthcare company that researches and develops a broad range of innovative pharmaceuticals, vaccines and consumer healthcare products. The company employs 100,000 people in 150 countries. Troy has been with the company since 2008. Prior to joining GSK, he was in private practice at the Washington, DC, firm of Sidley Austin. He has served as chief counsel for the U.S. Food & Drug Administration, where he served as a primary liaison to the White House and the U.S. Department of Health and Human Services.

Troy heads up a global legal organization at GSK that aligns lawyers with lines of business and practice areas, locates them in or close to GSK's major operations in Philadelphia, Belgium, and New Jersey, in addition to the company's commercial headquarters in Research Triangle Park, North Carolina and at head office in London. The legal department numbers 630, of whom 400 are lawyers. There are general counsels for the Vaccine and Consumer Healthcare businesses, research and development (R&D), and manufacturing and supply; there are three regional general counsels for the pharmaceutical business given its scale. Then there are also centralized pools of lawyers who specialize in litigation, patent, trademark, and general commercial work, all vital to GSK's success.

In order to work closely with his team and meet the needs of the business, Troy travels frequently, using his time in the air to work through his very large black bag of reading or occasionally enjoy an action movie. He says that communication, trust, and careful planning are key to making an organization of this scale work cohesively: "The most valuable commodity any of us have is our time. I try to be very thoughtful about how and where I spend my time. I know where I will be sleeping every night in 2017 to ensure the business runs smoothly."

"I'm based in GSK's office in Washington, DC, which means I don't sit in the same place as any of my direct reports; the relationships require lots of trust. My team operates with an enormous degree of autonomy, so I have to know we have the best possible people at all levels in our business, all aligned to our overall goal," he says. While the legal team is fully embedded within GSK and aligned to the business, Troy notes it is vitally important the function also maintains a distance: "We are independent but aligned." Troy sees Legal's role as helping the business solve problems, achieve what it wants and needs to achieve, providing guidance on staying safely within the limits of the law while also operating within the guardrails of GSK policy. "The more we know the business and the more we know about the business, the more we can help," he says.

Troy works closely with the other members of the corporate executive team in a similar, "very embedded, fully immersed" model. He says he needs to bring issues to the table that the executives might not always see or want to confront. He says he needs to "be both an advocate for the business but also to be a guardian, raising cautions about how society might react to various business decisions," while also clarifying what the law requires.

During Troy's eight-year tenure at GSK, the external environment for the pharmaceutical sector has changed significantly. For example, product liability risk used to be one of the main issues requiring GSK legal time, for now represents a much smaller business risk. Troy says his team is also currently thinking through some of the opportunities and challenges presented by the FDA's – and the court's – increased focus on the implications of the First Amendment for pharmaceutical regulation.

While the external environment has shifted during Troy's time at GSK, so too has the shape of the company itself. In March 2015, GSK completed an innovative three-part transaction with fellow pharmaceutical company Novartis, swapping GSK's marketed oncology portfolio for Novartis's vaccines business, with the two companies forming a joint venture in consumer healthcare. "Working on the Novartis transaction was an incredible opportunity to be involved in a transaction that would, could and did transform our company," Troy says. "To ensure confidentiality, we kept it very tight; not even ten lawyers in Legal knew about it, so senior people needed to roll up their sleeves and do some of the things that we hadn't done in years. It was very exciting."

In 2013, China's Ministry of Public Security began an investigation into working practices at GSK in China. During the subsequent investigation, Troy played an active role in advising the company's management team on how best to engage with the authorities during this investigation. Alongside the official investigation, Troy hired an external legal firm, Ropes and Gray, to conduct an independent investigation into what had happened in China. "This was an attorney-client-privileged investigation reporting to me, with my reporting to the Board and GSK's executive management team on their findings."

Since the conclusion of the investigation with the Chinese government, GSK has made significant changes to its business model globally, and was the first major pharmaceutical company to do so: GSK stopped paying sales representatives on the basis of prescription drug sales; and it stopped paying healthcare providers to speak on the company's behalf. "These not only reduced risk but were the right thing to do," Troy says. "The way the business embraced the business model changes helped the legal team persuade regulators that the business 'got it.'" While Legal played a valuable role, Troy notes these changes really came from within the business itself.

During his time at GSK, Troy has identified some significant differences between private practice and in-house practice. "In private practice, you only know what the internal counsel tells you. As that internal counsel, you get to see the whole context of the business, beginning, middle, and end," he says. He finds in-house practice extremely rewarding. "We are part of an organization that has as its mission to help people 'do more, feel better, live longer.' Every day, we interact with people who are discovering new medicines, making medicines, or helping to ensure that the appropriate medication is available to a patient who needs it, when they need it. I find this a more motivating environment than a law firm."

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Case ID: 181003237

A major innovation of which Troy—a sworn enemy of the billable hour—is proud is GSK’s Outside Counsel Selection Initiative (OCSI). Having brought 50 percent of GSK’s external legal spend under alternative fee arrangements by the end of his first year at the company, he then rolled out OCSI, a reverse online auction in which firms bid their best price for matters or portfolios of work.

"This work has been a major focus of my tenure. We use OCSI for every matter over \$250,000, and we have used it outside the United States," he says. "OCSI enables us to hire lawyers on a fairer, more data-driven, more objective basis. We take diversity into consideration when we hire outside firms. We track their progress and performance. It enables us to bring a variety of metrics and measures to bear to ensure that we are making our hiring decisions as transparently as possible, with respect for people and with integrity." Troy notes the selected firm is not always the lowest bidder, and GSK does negotiate frequently to ensure incentives are aligned between the company and outside counsel. He also emphasizes that the platform is open-source, and he is happy to share.

—Jennifer J. Salopek is a freelance writer based in McLean, Virginia. She can be reached at [jjsalopek@outlook.com](mailto:jjsalopek@outlook.com).

Not a member yet?   
Sign up for a free trial.

## **Exhibit B**



Menu

## Headquarters

Our global headquarters are in the UK but we also have a significant presence in the USA.

## Integrity and compliance contact details

GSK's [Speak Up Integrity Lines](#) can be used worldwide to report cases of unethical and illegal conduct. Please see our [global compliance page](#) for more details.



## UK - GSK House

980 Great West Road  
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Tel: [+44 \(0\)20 8047 5000](tel:+442080475000)

[Parking & directions to GSK House](#)

---



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[Visit the GSK US website](#)

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North Carolina

27709-3398

USA

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[Visit the GSK US website](#)

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GlaxoSmithKline plc. Registered in England and Wales No. 3888792.

Registered office: 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom.

## **Exhibit C**

**Relevant Excerpts from 2015 Annual Report of  
GlaxoSmithKline plc and its subsidiary undertakings**



do more  
feel better  
live longer

## Annual Report 2015

*2015 saw substantial progress to accelerate new product sales growth and strengthen our Pharmaceuticals, Vaccines and Consumer Healthcare businesses*



Case ID: 181003237

# Our investor proposition

GSK is a science-led global healthcare company that aims to deliver growth and improving returns to shareholders through the development of innovative pharmaceutical, vaccine and consumer healthcare products.

Strategic report

Governance &amp; remuneration

Financial statements

Investor information

## Three world-leading businesses

*Each has a broad range of growth drivers and the global presence to access increasing demand for healthcare.*



### Pharmaceuticals

**£14.2<sup>bn</sup>**

2015 turnover

Leadership in key therapeutic areas including Respiratory and HIV



### Vaccines

**£3.7<sup>bn</sup>**

2015 turnover

The most comprehensive vaccines portfolio in the industry



### Consumer Healthcare

**£6.0<sup>bn</sup>**

2015 turnover

One of the world's leading global Consumer Healthcare companies (by retail sales)

## Strong R&D innovation

*R&D underpins all our businesses with research focused in six core therapy areas.*



Vaccines



Respiratory diseases



Rare diseases



Immuno-inflammation



HIV/infectious diseases



Oncology

Around **40** new potential medicines and vaccines in our pipeline profiled at R&D event<sup>b</sup>

**80%** of which we believe are potentially first-in-class

**20** Potential to file up to 20 assets by 2020

<sup>b</sup> GSK R&D event on 3 November 2015.

## Efficient global operating model

*We are focused on optimising our operations through restructuring, investments and modernisation to improve profitability and efficiency.*

**£2.5<sup>bn</sup>**

2015 adjusted free cash flow excluding costs funded by divestments<sup>c</sup>

**£6.7<sup>bn</sup>**

net proceeds from disposals generated in 2015

**£3.7<sup>bn</sup>**

reduction in net debt in 2015

<sup>c</sup> Excluding legal payments and also non-core restructuring and integration costs and the initial tax payments on the sale of the Oncology business.

**£1<sup>bn</sup>**

in incremental annual cost savings delivered in 2015 and

**£3<sup>bn</sup>**

in annual cost savings expected by end of 2017<sup>d</sup>

<sup>d</sup> £1.6 billion annual savings achieved by 31 December 2015.



# Our Board

Strategic report



**Sir Philip Hampton** 62  
Non-Executive Chairman

**Nationality**  
British

**Appointment date**  
1 January 2015. Deputy Chairman from 1 April 2015 and Non-Executive Chairman from 7 May 2015

**Committee membership**  
Nominations Committee  
Chairman, Finance

## Skills and experience

Prior to joining GSK, Sir Philip chaired major FTSE 100 companies including The Royal Bank of Scotland Group plc and J Sainsbury plc. He has also served as Group Finance Director at Lloyds TSB Group, BT Group plc, BG Group plc, British Gas and British Steel plc. Sir Philip was previously appointed an Executive Director of Lazards and a Non-Executive Director at RMC Group Plc and Belgacom SA. Until 2009, he was Chairman of UK Financial Investments Limited, which manages the UK Government's shareholdings in banks.

## External appointments

Sir Philip is currently the Senior Independent Director of Anglo American Plc, Chairman of its Remuneration Committee and member of its Audit Committee. Sir Philip is also Chair of the Women on Board's review; an independent review on increasing representation of women in the executive level of FTSE 350 companies.

Governance &amp; remuneration



**Sir Andrew Witty** 51  
Chief Executive Officer

**Nationality**  
British

**Appointment date**  
31 January 2008 and as Chief Executive Officer on 21 May 2008

**Committee membership**  
Finance

## Skills and experience

Sir Andrew joined GSK in 1985. He has worked in the UK, South Africa, the US and Singapore in various senior roles. In 2003, he was appointed President of Europe and joined GSK's Corporate Executive Team. Andrew has served in numerous advisory roles to Governments around the world including South Africa, Singapore, Guangzhou China and the UK, where he was a member of the Prime Minister's Business Advisory Group from 2010-2015. He was awarded a Knighthood for services to the economy and to the UK pharmaceutical industry in the 2012 New Year Honours List.

## External appointments

Sir Andrew is appointed to the UK Business Ambassador Group, the China-Britain Business Council Advisory Council and the School of Economics & Management Advisory Board (SEM), Tsinghua University, Beijing, China. Sir Andrew is Chancellor of the University of Nottingham.

Financial statements



**Simon Dingemans** 52  
Chief Financial Officer

**Nationality**  
British

**Appointment date**  
4 January 2011 and as Chief Financial Officer on 1 April 2011

**Committee membership**  
Finance

## Skills and experience

Prior to joining GSK, Simon had over 25 years of experience in investment banking at SG Warburg and Goldman Sachs. During this time, he advised a broad range of large corporates across a number of industry sectors, including pharmaceuticals and consumer healthcare. Simon advised GSK for over a decade before his appointment and was closely involved in a number of GSK's key strategic projects.

## External appointments

Simon is Chairman of the 100 Group of Finance Directors.

Investor information



**Dr Moncef Slaoui** 56  
Chairman, Global Vaccines

**Nationality**  
Moroccan, Belgian & American

**Appointment date**  
17 May 2006

**Committee membership**  
Finance

## Skills and experience

Moncef joined GSK Vaccines in 1988 where he engineered the development of a robust vaccines pipeline. He then led Worldwide Business Development for pharmaceutical products before his appointment to lead R&D in 2006. He was given overall responsibility for GSK's Oncology Business in 2010; for GSK Vaccines in 2011; and for all Global Franchises in 2012. Moncef has advised the US President's Council of Advisors on Science and Technology and he was a member of the Board of the Agency for Science, Technology & Research (A\*STAR) until January 2011.

He has a PhD in Molecular Biology and Immunology from Université Libre de Bruxelles and has published more than 100 scientific papers and presentations. Prior to joining GSK, Moncef was Professor of Immunology at the University of Mons, Belgium.

## External appointments

Moncef is a member of the Biotechnology Industry Organization Board in the US and a member of the Advisory Committee to the Director of National Institutes of Health. He is also an adviser to the Qatar Foundation, and a member of the Qatar Biomedical Research Institute Scientific Advisory Committee. Moncef serves as a Non-Executive Director for the International AIDS Vaccine Initiative (IAVI).

**Sir Deryck Maughan** 68

Senior Independent  
Non-Executive Director

**Nationality**

British

**Appointment date**

1 June 2004 and as Senior  
Independent Non-Executive  
Director on 1 May 2013

**Committee membership**

Audit & Risk, Nominations,  
Remuneration and Finance

**Skills and experience**

Sir Deryck has a wealth of international corporate and investment banking experience, having previously served as Chairman and Chief Executive Officer of Citigroup International and of Salomon Brothers Inc. He served as Vice Chairman of the New York Stock Exchange from 1996 to 2000. Sir Deryck was a former Senior Adviser to, and Partner of, Kohlberg Kravis Roberts & Co and previously served as a Non-Executive Director of Thomson Reuters.

**External appointments**

Sir Deryck is a Non-Executive Director of BlackRock, Inc. and a Trustee of the British Museum.

**Professor Sir Roy Anderson** 68

Independent Non-Executive  
Director & Scientific Expert

**Nationality**

British

**Appointment date**

1 October 2007

**Committee membership**

Nominations and Finance

**Skills and experience**

Professor Sir Roy is a world-renowned medical scientist with advanced knowledge of infectious disease epidemiology, and is currently Professor of Infectious Disease in the Faculty of Medicine, Imperial College, London. He is a fellow of the Royal Society, the Academy of Medical Sciences and the Royal Statistical Society. He is an Honorary Fellow of the Institute of Actuaries and a Foreign Associate Member of the National Academy of Medicine at the US National Academy of Sciences and the French Academy of Sciences. Professor Sir Roy brings scientific expertise to the Board's deliberations.

**External appointments**

Professor Sir Roy is a member of the International Advisory Board of Holdingham Group and Chairman of the Science Advisory Board of the Natural History Museum, London. He is also a member of the Vaccine International Advisory Board (VACCIAB) of AJ Pharma Holding Sdn. Bhd in Malaysia.

**Manvinder Singh (Vindi) Banga** 61

Independent Non-Executive  
Director

**Nationality**

Indian

**Appointment date**

1 September 2015

**Committee membership**

Audit & Risk, Nominations,  
Remuneration and Finance

**Skills and experience**

Prior to joining GSK, Vindi spent 33 years at Unilever plc, where his last role (amongst several senior positions) was President of the Global Foods, Home and Personal Care businesses, and he was a member of the Unilever Executive Board. Vindi sat on the Prime Minister of India's Council of Trade & Industry from 2004 to 2014, and was on the Board of Governors of the Indian Institute of Management (IIM), Ahmedabad.

Vindi is also the recipient of the Padma Bhushan, one of India's highest civilian honours.

**External appointments**

Vindi is a partner at private equity investment firm Clayton Dubilier & Rice. He is also Chairman of the Supervisory Board of Mauser Group, Senior Independent Director of Marks & Spencer Group plc, and a member of its Nominations and Remuneration Committees. He is also a Non-Executive Director of Thompson Reuters Corp and a member of its HR Committee. Vindi is on the Governing Board of the Indian School of Business (ISB), Hyderabad.

**Dr Stephanie Burns** 61

Independent Non-Executive  
Director

**Nationality**

American

**Appointment date**

12 February 2007

**Committee membership**

Corporate Responsibility,  
Remuneration and Finance

**Skills and experience**

Stephanie is a recognised global business leader, having served as Chairman, President and CEO of Dow Corning Corporation until her retirement at the end of 2011. She has a strong scientific background, with a PhD in organic chemistry with an organosilicon speciality, and is an advocate for science education. Stephanie previously sat on the US President's Export Council and was an Officer of the Society of Chemical Industry, American Section, as well as the past Honorary President of the UK-based parent society. Stephanie was also an Officer and Chairman of the American Chemistry Council.

**External appointments**

Stephanie is a Non-Executive Director of Corning Inc. and of Kellogg Company, and was appointed to the Board of HP Inc. in November 2015.

## Our Board continued

Strategic report



**Stacey Cartwright** 52  
Independent Non-Executive  
Director

**Nationality**  
British

**Appointment date**  
1 April 2011

**Committee membership**  
Audit & Risk and Finance

### Skills and experience

Stacey is a Chartered Accountant and has significant experience of global consumer businesses and of corporate finance. She served as Executive Vice President, Chief Financial Officer of Burberry Group plc until July 2013. Prior to joining Burberry Group plc in 2004, Stacey held the role of Chief Financial Officer at Egg plc between 1999 and 2003, and from 1988 to 1999 she worked in various finance-related positions at Granada Group plc.

The Board has determined that Stacey has recent and relevant financial experience, and agreed that she has the appropriate qualifications and background to be an audit committee financial expert.

### External appointments

Stacey is Chief Executive Officer of Harvey Nichols Group of Companies.

Governance &amp; remuneration



**Lynn Elsenhans** 59  
Independent Non-Executive  
Director

**Nationality**  
American

**Appointment date**  
1 July 2012

**Committee membership**  
Corporate Responsibility  
Committee Chairman,  
Audit & Risk, Nominations  
and Finance

### Skills and experience

Lynn has a wealth of experience of running a global business and significant knowledge of the global markets in which GSK operates. She served as Chair, President and Chief Executive Officer of Sunoco Inc. from 2009 to 2012. Prior to joining Sunoco in 2008 as President and Chief Executive Officer, Lynn worked for Royal Dutch Shell which she joined in 1980 and where she held a number of senior roles, including Executive Vice President, Global Manufacturing from 2005 to 2008.

### External appointments

Lynn is a Non-Executive Director of Baker Hughes Inc. and Flowserve Corporation, a Director of the Texas Medical Center, and a Non-Executive Director of The First Tee of Greater Houston. She is also a Trustee of the United Way of Greater Houston.

Financial statements



**Dr Jesse Goodman** 64  
Independent Non-Executive  
Director & Scientific Expert

**Nationality**  
American

**Appointment date**  
1 January 2016

**Committee membership**  
Finance

### Skills and experience

Dr Goodman previously served in senior leadership positions at the US Food and Drug Administration (FDA), including most recently as FDA's Chief Scientist and previously as Deputy Commissioner for Science and Public Health and as Director of the Center for Biologics Evaluation and Research (CBER).

Dr Goodman played a leadership role in developing FDA's Regulatory Science and Medical Countermeasures Initiatives and has worked collaboratively with industry, academia, government and global public health and regulatory partners to prepare for and respond to major public health threats, including emerging infectious diseases, disasters and terrorism. He led FDA's response to West Nile Virus and to the 2009 H1N1 influenza pandemic and served on the Senior Leadership Team for the 2010 White House Medical Countermeasure Review. Dr Goodman brings scientific and public health expertise to the Board's deliberations.

### External appointments

Dr Goodman, currently Professor of Medicine at Georgetown University, directs the Georgetown University Center on Medical Product Access, Safety and Stewardship (COMPASS) and is an active clinician who serves as Attending Physician in Infectious Diseases. He also serves as President and Member of the Board of the United States Pharmacopeia (USP).

Investor information



**Judy Lewent** 67  
Independent Non-Executive  
Director

**Nationality**  
American

**Appointment date**  
1 April 2011

**Committee membership**  
Audit & Risk Committee  
Chairman, Nominations,  
Remuneration and Finance

### Skills and experience

Judy has extensive knowledge of the global pharmaceutical industry and of corporate finance, having joined Merck & Co. in 1980 and then served as Chief Financial Officer from 1990 to 2007 when she retired. Judy was previously a Non-Executive Director of Purdue Pharma Inc, Napp Pharmaceutical Holdings Limited and certain Mundipharma International Limited companies until 31 December 2014. Judy previously served as a Non-Executive Director of Dell Inc. and Quaker Oats Company.

The Board has determined that Judy has recent and relevant financial experience, and agreed that she has the appropriate qualifications and background to be an audit committee financial expert.

### External appointments

Judy is a Non-Executive Director of Thermo Fisher Scientific Inc. and Motorola Solutions Inc. She is also a Trustee of the Rockefeller Family Trust and Chairperson of the Audit Committee of Rockefeller Financial Services, a life member of the Massachusetts Institute of Technology Corporation and a member of the American Academy of Arts and Sciences.



**Dr Daniel Podolsky** 62  
Independent Non-Executive  
Director & Scientific Expert

**Nationality**  
American

**Appointment date**  
1 July 2006

**Committee membership**  
Audit & Risk, Corporate  
Responsibility and Finance

#### Skills and experience

Daniel is a world-renowned researcher who has advanced knowledge of underlying mechanisms of disease and new therapies for gastrointestinal disorders. He was formerly Mallinckrodt Professor of Medicine and Chief of Gastroenterology at Massachusetts General Hospital and Harvard Medical School, and previously served as the Chief Academic Officer of Partners Healthcare System. Daniel's current responsibilities in leading a large academic medical centre give him relevant insight into healthcare delivery. Daniel brings scientific expertise to the Board and the Audit & Risk Committee's deliberations.

#### External appointments

Daniel is President of the University of Texas Southwestern Medical Center and holds the Philip O'Bryan Montgomery, Jr., M.D. Distinguished Presidential Chair in Academic Administration, and the Doris and Bryan Wildenthal Distinguished Chair in Medical Science. He is a member of the National Academy of Medicine at the US National Academy of Sciences, member of the Board of the Southwestern Medical Foundation and a Director of Antibiotics, Inc.

He is also a member of the National Academies of Sciences Board on Army Science and Technology.



**Urs Rohner** 56  
Independent Non-Executive  
Director

**Nationality**  
Swiss

**Appointment date**  
1 January 2015

**Committee membership**  
Remuneration Committee  
Chairman and Finance

#### Skills and experience

Urs has a broad range of business and legal experience having served as Chairman on a number of Boards, most recently for Credit Suisse, a world leading financial services company. Prior to joining Credit Suisse in 2004, Urs served as Chairman of the Executive Board and CEO of ProSieben and ProSiebenSat.1 Media AG. This followed a number of years in private practice at major law firms in Switzerland and the US, having been admitted to the bars of the canton of Zurich in 1986 and the state of New York in 1990.

#### External appointments

Urs is currently appointed Chairman of the Board of Credit Suisse Group AG and of the Chairman's and Governance Committee. He is also appointed Chairman and member of the Board of Trustees of Credit Suisse Research Institute and Credit Suisse Foundation. Urs was appointed Vice-Chairman of the Governing Board of the Swiss Bankers Association in 2015.



**Hans Wijers** 65  
Independent Non-Executive  
Director

**Nationality**  
Dutch

**Appointment date**  
1 April 2013

**Committee membership**  
Corporate Responsibility,  
Remuneration and Finance

#### Skills and experience

Hans has a broad range of business, economic and political experience, having served as Chief Executive Officer and Chairman at Akzo Nobel NV from 2002 to 2012. Hans had a long and distinguished career in academia, public service and strategy consulting. He served as Senior Partner of the Boston Consulting Group from 1998 to 2002.

#### External appointments

Hans is Chairman of the Supervisory Board of Heineken NV and also Deputy Chairman and Non-Executive Director of Royal Dutch Shell. He is Chairman of the Supervisory Board of AFC Ajax and member of the Supervisory Board of HAL Holding N.V.

# Our Corporate Executive Team

Our CEO, with the assistance of the Corporate Executive Team, is responsible for the management of the business, developing the Group's strategic direction for consideration and approval by the Board and implementing the agreed strategy.



**Sir Andrew Witty**  
Chief Executive Officer\*



**Simon Dingemans**  
Chief Financial Officer\*



**Dr Moncef Slaoui**  
Chairman, Global Vaccines\*

\*For biographical details, see page 74.



**Roger Connor**  
President, Global Manufacturing & Supply  
Roger joined CET in 2012 and was appointed as President, Global Manufacturing & Supply (GMS) in 2013, after working for a year as President Designate, GMS.

Roger joined GSK in 1998 from AstraZeneca and has worked in finance and manufacturing strategy roles, including at GSK sites in Cork in Ireland and Ware in the UK. Prior to his position in GMS, Roger was Vice President, Office of the CEO and Corporate Strategy, from February 2010.

He holds a degree in Mechanical and Manufacturing Engineering from Queen's University Belfast and a Masters in Manufacturing Leadership from Cambridge University. He is also a Chartered Accountant.



**Nick Hiron**  
Senior Vice President, Global Ethics and Compliance  
Nick was appointed to CET in September 2014 as Senior Vice President, Global Ethics and Compliance and is responsible for compliance, risk management and corporate security and investigations.

Nick joined GSK in 1994 as an International Auditor in the UK. He was later Head of Audit & Assurance, where he combined five separate audit functions into an independent team operating with a common risk-based methodology. In June 2013, Nick took up a role in China, where he established a new governance model for our China business that created a consistent approach to compliance.

Nick is a fellow of the Chartered Institute of Management Accountants.



**Abbas Hussain**  
President, Global Pharmaceuticals  
Abbas joined CET in 2008 and was appointed President, Global Pharmaceuticals in October 2014, having joined the company as President, Emerging Markets & Asia Pacific in June 2008. He joined the ViiV Healthcare Ltd. Board in October 2009.

Previously, he spent 20 years at Eli Lilly where he held positions including President, Europe and before that Vice President, Europe. He also held positions with Eli Lilly in Australia, the US, India, Turkey and Germany in several roles including business development, sales and marketing, and management.

He has a degree in Medicinal Chemistry & Pharmacology from Loughborough University and was born in Madras, India.



### David Redfern

Chief Strategy Officer

David joined CET as Chief Strategy Officer in May 2008 and is responsible for corporate development and strategic planning. In addition, he was appointed Chairman of the Board of ViiV Healthcare Ltd. in April 2011 and a Non-Executive Director of the Aspen Pharmacare Ltd. Board in February 2015.

Previously, he was Senior Vice President, Northern Europe with responsibility for GSK's pharmaceutical businesses in that region and, prior to that, was Senior Vice President for Central and Eastern Europe. David joined GSK in 1994 and was Finance Director of the European business from 1999 to 2002.

David has a Bachelor of Science degree from Bristol University in the UK and is a Chartered Accountant.



### Claire Thomas

Senior Vice President, Human Resources

Claire was appointed to CET as Senior Vice President, Human Resources in May 2008.

Claire joined the company in 1996 as Senior Manager, Human Resources, Sales and Marketing Group, UK Pharmaceuticals before becoming Director of Human Resources for UK Pharmaceuticals in 1997. She was appointed Senior Vice President, Human Resources, Pharmaceuticals Europe in 2001, and Senior Vice President Human Resources International in 2006.

Prior to joining the company she worked for Ford Motor Company, holding various positions in Human Resources.

Claire has a Bachelor of Science degree in Economics, Management and Industrial Relations from the University of Wales.



### Phil Thomson

Senior Vice President, Communications and Government Affairs

Phil joined CET in 2011 and was appointed Senior Vice President, Communications and Government Affairs in 2014. He has responsibility for Media Relations, Investor Relations, Corporate Responsibility, Internal Communications, Product Communications, Government Affairs and GSK's Global Brand.

He joined Glaxo Wellcome as a trainee in 1996, moving from pharmaceutical brand marketing to product communications. In 1999, he became Director of Media Relations for Glaxo Wellcome plc and was then Director, Investor Relations from 2001 to 2004, when he returned to Corporate Media Relations as Vice President. Phil has worked on numerous corporate, product and reputational matters at GSK.

Phil earned his degree in English and History from Durham University.



### Dan Troy

Senior Vice President & General Counsel

Dan joined GSK and the CET as Senior Vice President & General Counsel in September 2008.

He was previously a Partner at the Washington law firm Sidley Austin LLP, where he represented mainly pharmaceutical companies and trade associations on matters related to the US Food and Drug Administration (FDA) and government regulations. Dan was formerly Chief Counsel for the FDA, where he served as a primary liaison to the White House and the US Department of Health and Human Services.

Dan is a graduate from Cornell University's School of Industrial and Labor Relations, and earned his law degree from Columbia University School of Law. Dan was named a 'Legend in the Law' at the Burton Awards.



### Patrick Vallance

President, Pharmaceuticals R&D

Patrick joined CET in 2010 and was appointed President, Pharmaceuticals R&D, in January 2012. Prior to this he was Senior Vice President, Medicines Discovery and Development.

Patrick joined the company in 2006 as Head of Drug Discovery. Prior to joining GSK Patrick was a clinical academic and led the Division of Medicine at University College London. He has over 20 years' experience of research clinical medicine, general internal medicine, cardiovascular medicine and clinical pharmacology. He was elected to the Academy of Medical Sciences in 1999.

Patrick has been on the Board of the UK Office for Strategic Co-ordination of Health Research (OSCHR) since 2009.



### Emma Walmsley

CEO, GSK Consumer Healthcare

Emma is CEO of GSK Consumer Healthcare, which includes the joint venture with Novartis and the listed Consumer Healthcare businesses in India and Nigeria. The business is split almost equally between OTC medicines and fast moving consumer goods brands, across four categories of Wellness, Oral health, Nutrition and Skin health.

Prior to this Emma was President of GSK Consumer Healthcare and has been a member of CET since 2011. She joined GSK in 2010.

Prior to this, Emma worked with L'Oreal for 17 years. She has a degree in Classics and Modern Languages from Oxford University.

Emma became a non-executive director of Diageo plc with effect from 1 January 2016.

## 44 Principal Group companies

The following represent the principal subsidiaries and their countries of incorporation of the Group at 31 December 2015. The equity share capital of these entities is wholly owned by the Group except where its percentage interest is shown otherwise. All companies are incorporated in their principal country of operation except where stated.

### England

Glaxo Group Limited  
Glaxo Operations UK Limited  
GlaxoSmithKline Capital plc  
GlaxoSmithKline Consumer Healthcare Holdings Limited (63.5%)  
GlaxoSmithKline Consumer Healthcare (UK) Trading Limited (63.5%)  
GlaxoSmithKline Export Limited  
GlaxoSmithKline Finance plc  
GlaxoSmithKline Holdings Limited \*  
GlaxoSmithKline Research & Development Limited  
GlaxoSmithKline Services Unlimited \*  
GlaxoSmithKline UK Limited  
Setfirst Limited  
SmithKline Beecham Limited  
ViiV Healthcare Limited (78.3%)  
ViiV Healthcare UK Limited (78.3%)

### Europe

GlaxoSmithKline Biologicals S.A. (Belgium)  
GlaxoSmithKline Pharmaceuticals S.A. (Belgium)  
GlaxoSmithKline Biologicals S.A.S. (France)  
Groupe GlaxoSmithKline S.A.S. (France)  
Laboratoire GlaxoSmithKline S.A.S. (France)  
ViiV Healthcare S.A.S. (France) (78.3%)  
GlaxoSmithKline Consumer Healthcare GmbH & Co. KG (Germany) (63.5%)  
GlaxoSmithKline GmbH & Co. KG (Germany)  
Novartis Consumer Health GmbH (Germany) (63.5%)  
GlaxoSmithKline Consumer Healthcare S.p.A. (Italy) (63.5%)  
GlaxoSmithKline S.p.A. (Italy)  
GlaxoSmithKline B.V. (Netherlands)  
GlaxoSmithKline Pharmaceuticals S.A. (Poland)  
GSK Services Sp.z.o.o. (Poland)  
GlaxoSmithKline Trading Services Limited (Republic of Ireland) (i)  
GlaxoSmithKline S.A. (Spain)  
Novartis Consumer Health S.A. (Switzerland) (63.5%)

### US

Block Drug Company, Inc.  
Corixa Corporation  
GlaxoSmithKline Capital Inc.  
GlaxoSmithKline Consumer Healthcare, L.P. (55.9%)  
GlaxoSmithKline Holdings (Americas) Inc.  
GlaxoSmithKline LLC  
Human Genome Sciences, Inc.  
Novartis Consumer Health, Inc.  
Stiefel Laboratories, Inc.  
ViiV Healthcare Company (78.3%)

### Others

GlaxoSmithKline Argentina S.A. (Argentina)  
GlaxoSmithKline Australia Pty Ltd. (Australia)  
GlaxoSmithKline Brasil Limitada (Brazil)  
GlaxoSmithKline Inc. (Canada)  
ID Biomedical Corporation of Quebec (Canada)  
GlaxoSmithKline (China) Investment Co. Ltd. (China)  
GlaxoSmithKline Limited (China)  
GlaxoSmithKline Pharmaceuticals (Suzhou) Limited (China)  
Sino-American Tianjin Smith Kline & French Laboratories Ltd. (China) (34.9%)  
GlaxoSmithKline Consumer Healthcare Limited (India) (72.5%)  
GlaxoSmithKline Pharmaceuticals Limited (India) (75%)  
GlaxoSmithKline Consumer Healthcare Japan K.K. (Japan)  
GlaxoSmithKline K.K. (Japan)  
GlaxoSmithKline Mexico S.A. de C.V. (Mexico)  
GlaxoSmithKline Pakistan Limited (Pakistan) (82.6%)  
Glaxo Wellcome Manufacturing Pte Ltd. (Singapore)  
GlaxoSmithKline Pte Ltd. (Singapore)  
GlaxoSmithKline Korea Limited (South Korea)  
GlaxoSmithKline Ilaciları Sanayi ve Ticaret A.S. (Turkey)

- (i) Exempt from the provisions of section 347 and 348 of the Companies Act 2014 (Ireland), in accordance with the exemptions noted in Section 357 of that Act. Further subsidiaries, as disclosed on pages 250 to 258, are exempt from these provisions as they are also consolidated in the group financial statements.

\* Directly held wholly owned subsidiary of GlaxoSmithKline plc.

The subsidiaries and associates listed above principally affect the figures in the Group's financial statements. Each of GlaxoSmithKline Capital Inc. and GlaxoSmithKline Capital plc is a wholly-owned finance subsidiary of the company, and the company has fully and unconditionally guaranteed the securities issued by each of GlaxoSmithKline Capital Inc. and GlaxoSmithKline Capital plc.

See pages 250 to 258 for a complete list of subsidiary undertakings, associates and joint ventures, which form part of these financial statements.

# Other statutory disclosures

## continued

### Group companies

In accordance with Section 409 of the Companies Act 2006 a full list of subsidiaries, associates, joint ventures and joint arrangements, the country of incorporation and effective percentage of equity owned, as at 31 December 2015 are disclosed below. Unless otherwise stated the share capital disclosed comprises ordinary shares which are indirectly held by GlaxoSmithKline plc. All subsidiary companies are resident for tax purposes in their country of incorporation unless otherwise stated.

Name	Country of incorporation	Effective % Ownership	Security	% Held by Class of Share
<b>Wholly owned subsidiaries</b>				
1506369 Alberta ULC	Canada	100	Common	100
Action Potential Venture Capital Limited	England & Wales	100	Ordinary	100
Adechsa GmbH	Switzerland	100	Ordinary	100
Affymax Research Institute	United States	100	Common	100
Alenfarma – Especialidades Farmaceuticas, Limitada (iv)	Portugal	100	Ordinary Quota	100
Allen & Hanburys Limited (iv)	England & Wales	100	Ordinary	100
Allen & Hanburys Pharmaceutical Nigeria Limited	Nigeria	100	Ordinary	100
Allen Farmaceutica, S.A.	Spain	100	Ordinary	100
Allen Pharmazeutika Gesellschaft m.b.H.	Austria	100	Ordinary	100
Aners S.A (iv)	Argentina	100	Non-endorsable Nominative	
			Ordinary	100
Barrier Therapeutics, Inc.	United States	100	Common	100
Beecham Group plc	England & Wales	100	20p Shares 'A'; 5p Shares B	100
Beecham Pharmaceuticals (Pte) Limited	Singapore	100	Ordinary	100
Beecham Pharmaceuticals S.A (iv) (vi)	Ecuador	100	Nominative	100
Beecham Portuguesa-Produtos Farmaceuticos e Quimicos, Lda	Portugal	100	Ordinary Quota	100
Beecham S.A. (iv)	Belgium	100	Ordinary	100
Biddle Sawyer Limited	India	100	Equity	100
Biovesta Ilaçları Ltd. Sti.	Turkey	100	Nominative	100
Burroughs Wellcome & Co (Australia) Pty Limited (iv) (vi)	Australia	100	Ordinary	100
Burroughs Wellcome & Co (Bangladesh) Limited	Bangladesh	100	Ordinary	100
Burroughs Wellcome International Limited	England & Wales	100	Ordinary	100
Caribbean Chemical Company, Ltd. (will be struck off on 31.03.16)	Cayman Islands	100	Ordinary	100
Cascan GmbH & Co. KG	Germany	100	Ordinary	100
Castleton Investment Ltd (vi)	Mauritius	100	Ordinary	100
Cellzome GmbH	Germany	100	Ordinary	100
Cellzome Limited	England & Wales	100	Ordinary	100
Cellzome Therapeutics, Inc. (iv)	United States	100	Ordinary	100
Cellzome, Inc.	United States	100	Ordinary	100
			Series A Preferred	100
			Series B Preferred	100
			Series C-1 Convertible Preferred	100
			Series C-3 Convertible Preferred	100
Charles Midgley Limited (iv)	England & Wales	100	Ordinary	100
			Cumulative Preference	100
Clarges Pharmaceuticals Limited	England & Wales	100	Ordinary	100
			Preference	99.97
Colleen Corporation	United States	100	Shares – No Par Value (Common)	100
Corixa Corporation	United States	100	Common	100
Coulter Pharmaceutical, Inc. (iv)	United States	100	Common	100
Dealcyber Limited	England & Wales	100	Ordinary	100
Desarrollo Energia Solar Alternativa S.L.	Spain	100	Ordinary	100
Domantis Limited	England & Wales	100	Ordinary	100
Duncan Flockhart Australia Pty Limited (iv) (vi)	Australia	100	Ordinary	100
Duncan Pharmaceuticals Philippines Inc.	Philippines	100	Common	100
Edinburgh Pharmaceutical Industries Limited	Scotland	100	Ordinary; Preference	100
Eskaylab Limited	England & Wales	100	10p Ordinary	100
Etex Farmaceutica Ltda	Chile	100	Social Capital	100
Europharm Holding S.A.	Romania	100	Nominative	100
Europharm S.A.	Romania	100	Nominative	100
Fedialis Medica S.A.S.	France	100	Ordinary	100
Fipar (Thailand) Ltd (In liquidation)	Thailand	100	Ordinary	100
Genelabs Technologies, Inc.	United States	100	Common	100
Glaxo AS (iv)	Norway	100	Ordinary	100
Glaxo Group Limited	England & Wales	100	Ordinary	100
Glaxo Kabushiki Kaisha (iv)	Japan	100	Ordinary	100

## Group companies continued

Name	Country of incorporation	Effective % Ownership	Security	% Held by Class of Share
<b>Wholly owned subsidiaries continued</b>				
Glaxo Laboratories (Nigeria) Limited (iv)	Nigeria	100	Ordinary	100
Glaxo Laboratories Limited (iv)	England & Wales	100	Ordinary	100
Glaxo Operations UK Limited	England & Wales	100	Ordinary	100
Glaxo Properties BV	Netherlands	100	Ordinary	100
Glaxo Verwaltungs GmbH (vi)	Germany	100	Ordinary	100
Glaxo Wellcome Australia Pty Ltd (iv) (vi)	Australia	100	Ordinary	100
Glaxo Wellcome Ceylon Limited	Sri Lanka	100	Ordinary	100
			Ordinary B	100
Glaxo Wellcome Farmaceutica, Limitada	Portugal	100	Ordinary Quota	100
Glaxo Wellcome Holdings Limited (In liquidation)	England & Wales	100	Ordinary	100
Glaxo Wellcome International B.V. (v)	Netherlands	100	Ordinary	100
Glaxo Wellcome Manufacturing Pte Ltd	Singapore	100	Ordinary	100
Glaxo Wellcome Production S.A.S.	France	100	Ordinary	100
Glaxo Wellcome PST Pty Ltd (iv) (vi)	Australia	100	Ordinary	100
Glaxo Wellcome UK Limited	England & Wales	100	Ordinary	100
Glaxo Wellcome Vidhyasom Limited (iv)	Thailand	100	Ordinary	100
Glaxo Wellcome, S.A.	Spain	100	Ordinary	100
Glaxo, S.A.	Spain	100	Ordinary	100
Glaxo-Allenburys (Nigeria) Limited (iv)	Nigeria	100	Ordinary	100
Glaxochem (UK) Unlimited	England & Wales	100	Ordinary	100
			Ordinary B	100
			Ordinary C	100
Glaxochem Pte Ltd (v)	Singapore	100	Ordinary	100
GlaxoSmithKline – Produtos Farmaceuticos, Limitada	Portugal	100	Ordinary Quota	100
GlaxoSmithKline (Cambodia) Co., Ltd.	Cambodia	100	Ordinary	100
GlaxoSmithKline (China) Investment Co Ltd	China	100	Ordinary	100
GlaxoSmithKline (China) R&D Company Limited	China	100	Equity	100
GlaxoSmithKline (Cyprus) Limited	Cyprus	100	Ordinary	100
GlaxoSmithKline (GSK) S.R.L.	Romania	100	Ordinary	100
GlaxoSmithKline (Ireland) Limited (ii)	Ireland	100	Ordinary	100
GlaxoSmithKline (Israel) Ltd	Israel	100	Ordinary	100
GlaxoSmithKline (Malta) Limited	Malta	100	Ordinary	100
GlaxoSmithKline (Private) Limited (iv)	Zimbabwe	100	Ordinary	100
GlaxoSmithKline (Thailand) Limited	Thailand	100	Ordinary	100
GlaxoSmithKline A.E.B.E.	Greece	100	Ordinary	100
GlaxoSmithKline AB	Sweden	100	Ordinary	100
GlaxoSmithKline AG	Switzerland	100	Ordinary	100
GlaxoSmithKline Algérie S.P.A.	Algeria	100	Ordinary	100
GlaxoSmithKline Argentina S.A.	Argentina	100	Ordinary	100
GlaxoSmithKline AS	Norway	100	Ordinary	100
GlaxoSmithKline Asia Pvt. Limited	India	100	Equity	100
GlaxoSmithKline Australia Pty Ltd	Australia	100	Ordinary	100
GlaxoSmithKline B.V.	Netherlands	100	Ordinary	100
GlaxoSmithKline Beteiligungs GmbH	Germany	100	Ordinary	100
GlaxoSmithKline Biologicals (Shanghai) Ltd.	China	100	Ordinary	100
GlaxoSmithKline Biologicals (Shenzhen) Co., Ltd (iv)	China	100	Ordinary	100
GlaxoSmithKline Biologicals Kft.	Hungary	100	Ordinary	100
GlaxoSmithKline Biologicals S.A.S.	France	100	Ordinary	100
GlaxoSmithKline Biologicals SA	Belgium	100	Ordinary; Preference	100
GlaxoSmithKline Brasil Limitada	Brazil	100	Ordinary	100
GlaxoSmithKline Business Services S.A. (iv) (vi)	Costa Rica	100	Ordinary	100
GlaxoSmithKline Capital Inc.	United States	100	Ordinary	100
GlaxoSmithKline Capital plc	England & Wales	100	Ordinary	100
GlaxoSmithKline Caribbean Limited	England & Wales	100	Ordinary	100
GlaxoSmithKline Chile Farmaceutica Limitada	Chile	100	Social Capital	100
GlaxoSmithKline Colombia S.A.	Colombia	100	Ordinary	100
GlaxoSmithKline Consumer Healthcare Investments (Ireland) Limited (ii) (v)	Ireland	100	Ordinary	100
GlaxoSmithKline Consumer Healthcare Ireland IP Limited (ii) (v)	Ireland	100	Ordinary	100
GlaxoSmithKline Consumer Healthcare Pakistan Limited	Pakistan	100	Ordinary	100
GlaxoSmithKline Consumer Healthcare Sri Lanka Holdings Limited (iv)	England & Wales	100	Ordinary	100
GlaxoSmithKline Consumer Holding B.V.	Netherlands	100	Ordinary	100
GlaxoSmithKline d.o.o	Bosnia and Herzegovina	100	Euro Quota	100

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<b>Wholly owned subsidiaries continued</b>				
GlaxoSmithKline d.o.o.	Croatia	100	Equity	100
GlaxoSmithKline doo Beograd	Serbia	100	Ordinary	100
GlaxoSmithKline Ecuador S.A.	Ecuador	100	Ordinary	100
GlaxoSmithKline Eesti OU	Estonia	100	Ordinary	100
GlaxoSmithKline ehf	Iceland	100	Ordinary	100
GlaxoSmithKline El Salvador S.A. de C.V.	El Salvador	100	Ordinary	100
GlaxoSmithKline EOOD	Bulgaria	100	Ordinary	100
GlaxoSmithKline Export Limited	England & Wales	100	Ordinary	100
GlaxoSmithKline Export Panama S.A.	Panama	100	Ordinary	100
GlaxoSmithKline Far East B.V.	Netherlands	100	Ordinary	100
GlaxoSmithKline Finance plc	England & Wales	100	Ordinary	100
GlaxoSmithKline GmbH & Co. KG	Germany	100	Partnership Capital	100
GlaxoSmithKline Guatemala S.A.	Guatemala	100	Ordinary	100
GlaxoSmithKline Holding AS	Norway	100	Ordinary	100
GlaxoSmithKline Holdings (Americas) Inc.	United States	100	Common	100
GlaxoSmithKline Holdings (Ireland) Limited	England & Wales	100	Ordinary; Deferred	100
GlaxoSmithKline Holdings (One) Limited (i)	England & Wales	100	Ordinary	100
GlaxoSmithKline Holdings Limited (i)	England & Wales	100	Ordinary	100
GlaxoSmithKline Holdings Pty Ltd	Australia	100	Ordinary	100
GlaxoSmithKline Honduras S.A.	Honduras	100	Ordinary	100
GlaxoSmithKline IHC Limited	England & Wales	100	Ordinary	100
GlaxoSmithKline Ilaclari Sanayi ve Ticaret A.S.	Turkey	100	Nominative	100
GlaxoSmithKline Inc.	Canada	100	Class A Common	100
			Class C Preference	100
GlaxoSmithKline Insurance Ltd.	Bermuda	100	Ordinary	100
GlaxoSmithKline Intellectual Property (No.2) Limited	England & Wales	100	Ordinary	100
GlaxoSmithKline Intellectual Property Development Limited	England & Wales	100	Ordinary	100
GlaxoSmithKline Intellectual Property Holdings Limited	England & Wales	100	A Ordinary; B Ordinary	100
GlaxoSmithKline Intellectual Property Limited	England & Wales	100	Ordinary; Deferred	100
GlaxoSmithKline Intellectual Property Management Limited	England & Wales	100	Ordinary	100
GlaxoSmithKline International Limited	England & Wales	100	Ordinary	100
GlaxoSmithKline Investigación y Desarrollo, S.L.	Spain	100	Ordinary	100
GlaxoSmithKline Investment Holdings Limited	England & Wales	100	Ordinary	100
GlaxoSmithKline Investment Services Limited	England & Wales	100	Ordinary	100
GlaxoSmithKline Investments (Ireland) Limited (ii) (v)	Ireland	100	Ordinary	100
GlaxoSmithKline Investments Pty Ltd	Australia	100	Ordinary	100
GlaxoSmithKline K.K.	Japan	100	Ordinary	100
GlaxoSmithKline Korea Limited	South Korea	100	Ordinary	100
GlaxoSmithKline Latin America, S.A.	Panama	100	Ordinary	100
GlaxoSmithKline Latvia SIA	Latvia	100	Ordinary	100
GlaxoSmithKline Lietuva UAB	Lithuania	100	Ordinary	100
GlaxoSmithKline Limited	Hong Kong	100	Ordinary	100
GlaxoSmithKline LLC	United States	100	LLC Interests	100
GlaxoSmithKline Manufacturing SpA	Italy	100	Ordinary	100
GlaxoSmithKline Maroc S.A.	Morocco	100	Ordinary	100
GlaxoSmithKline Medical and Healthcare Products Limited	Hungary	100	Ordinary Quotas	100
GlaxoSmithKline Mercury Limited (i)	England & Wales	100	Ordinary	100
GlaxoSmithKline Mexico S.A. de C.V.	Mexico	100	Ordinary A; Ordinary B	100
GlaxoSmithKline NZ Limited	New Zealand	100	Ordinary	100
GlaxoSmithKline Oy	Finland	100	Ordinary	100
GlaxoSmithKline Peru S.A.	Peru	100	Ordinary	100
GlaxoSmithKline Pharma A/S	Denmark	100	Class A	100
GlaxoSmithKline Pharma GmbH	Austria	100	Ordinary	100
GlaxoSmithKline Pharmaceutical Kenya Limited	Kenya	100	Ordinary	100
GlaxoSmithKline Pharmaceutical Nigeria Limited	Nigeria	100	Ordinary	100
GlaxoSmithKline Pharmaceutical Sdn Bhd	Malaysia	100	Ordinary	100
GlaxoSmithKline Pharmaceuticals (Pvt) Ltd (iv)	Sri Lanka	100	Ordinary	100
GlaxoSmithKline Pharmaceuticals (Suzhou) Limited	China	100	Ordinary	100
GlaxoSmithKline Pharmaceuticals Costa Rica S.A.	Costa Rica	100	Ordinary	100
GlaxoSmithKline Pharmaceuticals S.A.	Poland	100	Ordinary A; Ordinary B; Ordinary C; Ordinary D	100

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<b>Wholly owned subsidiaries continued</b>				
GlaxoSmithKline Pharmaceuticals SA	Belgium	100	Ordinary	100
GlaxoSmithKline Pharmaceuticals Ukraine LLC	Ukraine	100	Chartered Capital	100
GlaxoSmithKline Philippines Inc	Philippines	100	Common	100
GlaxoSmithKline Pte Ltd	Singapore	100	Ordinary	100
GlaxoSmithKline Puerto Rico Inc. (iv)	Puerto Rico	100	Common	100
GlaxoSmithKline Republica Dominicana S.A.	Dominican Republic	100	Ordinary	100
GlaxoSmithKline Research & Development Limited	England & Wales	100	Ordinary	100
GlaxoSmithKline S.A.	Spain	100	Ordinary	100
GlaxoSmithKline S.p.A.	Italy	100	Ordinary	100
GlaxoSmithKline s.r.o.	Czech Republic	100	Ordinary	100
GlaxoSmithKline Services GmbH & Co. KG (vi)	Germany	100	Partnership Capital	100
GlaxoSmithKline Services Inc. (iv)	United States	100	Common	100
GlaxoSmithKline Services Unlimited (i)	England & Wales	100	Ordinary	100
GlaxoSmithKline SL Holdings, LLC	United States	100	LLC Interests	100
GlaxoSmithKline SL LLC	United States	100	LLC Interests	100
GlaxoSmithKline SL LP (iv)	England & Wales	100	Partnership	100
GlaxoSmithKline Slovakia s.r.o.	Slovakia	100	Ordinary	100
GlaxoSmithKline South Africa (Pty) Limited	South Africa	100	Ordinary	100
GlaxoSmithKline Superannuation Company Pty Ltd (iv) (vi)	Australia	100	Ordinary	100
GlaxoSmithKline Trading Services Limited (ii) (v)	Ireland	100	Ordinary	100
GlaxoSmithKline Trading ZAO	Russia	100	Ordinary	100
GlaxoSmithKline Tunisia S.A.R.L.	Tunisia	100	Ordinary	100
GlaxoSmithKline UK Limited	England & Wales	100	Ordinary	100
GlaxoSmithKline Uruguay S.A.	Uruguay	100	Registered Shares Provisory Stock	100
GlaxoSmithKline Venezuela C.A.	Venezuela	100	Ordinary	100
GlaxoSmithKline Vietnam Limited Liability Company (iv)	Vietnam	100	Equity Capital	100
Glycovaxyn AG (iv) (vi)	Switzerland	100	Common; Preferred A, Preferred B; Preferred C	100
Group Laboratories South Africa (Pty) Limited (iv) (vi)	South Africa	100	Ordinary	100
Groupe GlaxoSmithKline S.A.S.	France	100	Ordinary	100
GSK Business Service Centre Sdn Bhd	Malaysia	100	Ordinary	100
GSK Commercial Sp. z o.o.	Poland	100	Ordinary	100
GSK d.o.o., Ljubljana	Slovenia	100	Ordinary	100
GSK Employee Share Plan Pty Ltd	Australia	100	Ordinary	100
GSK Kazakhstan LLP	Kazakhstan	100	Partnership Interest	100
GSK Services Sp z o.o.	Poland	100	Ordinary	100
GSK Vaccines GmbH	Germany	100	Ordinary	100
GSK Vaccines Institute for Global Health S.r.l.	Italy	100	Quota	100
GSK Vaccines S.r.l.	Italy	100	Quota	100
GSK Vaccines Vertriebs GmbH	Germany	100	Ordinary	100
Herbridge (ii) (iv) (vi)	Ireland	100	Ordinary	100
HGS France S.a.r.l.	France	100	Ordinary	100
HGS Luxembourg LLC (iv) (vi)	United States	100	Common Interests	100
Horlicks Limited	England & Wales	100	Ordinary	100
Human Genome Sciences Pacific Pty Ltd (vi)	Australia	100	Ordinary	100
Human Genome Sciences, Inc.	United States	100	Common	100
ID Biomedical Corporation of Quebec	Canada	100	Common	100
ID Biomedical Corporation of Washington (iv)	United States	100	Common	100
Instituto Luso Farmaco, Limitada (iv)	Portugal	100	Ordinary Quota	100
InterPharma Dienstleistungen GmbH	Austria	100	Quota	100
J&J Technologies, LC (iv)	United States	100	Membership Interest	100
Laboratoire GlaxoSmithKline	France	100	Ordinary	100
Laboratoire Pharmaceutique Algérien LPA Production SPA	Algeria	100	Ordinary	100
Laboratoire Pharmaceutique Algérien SPA	Algeria	100	Ordinary	100
Laboratoires Paucourt (iv)	France	100	Ordinary	100
Laboratoires Saint-Germain (iv)	France	100	Ordinary	100
Laboratorios Dermatologicos Darier, S.A de C.V.	Mexico	100	Ordinary A; Ordinary B	100
Laboratorios Farmaceuticos Stiefel (Portugal) LTDA (iv)	Portugal	100	Ordinary Quota	100
Laboratorios Phoenix Sociedad Anonima Industrial Comercial Y Financiera	Argentina	100	Non-endorsable Nominative Ordinary Shares	100
Laboratorios Stiefel de Chile & CIA LTDA	Chile	100	Social Capital	100
Laboratorios Stiefel de Venezuela SA	Venezuela	100	Ordinary	100

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<b>Wholly owned subsidiaries continued</b>				
Laboratorios Stiefel Ltda.	Brazil	100	Ordinary	100
Laboratorios Wellcome De Portugal Limitada (iv)	Portugal	100	Ordinary Quota	100
Laboratorios Wellcome S.A. (In liquidation)	Uruguay	100	Ordinary	100
Maxinutrition Limited (In liquidation)	England & Wales	100	Ordinary	100
Mixis Genetics Limited	England & Wales	100	Ordinary	100
			Ordinary Euro	100
Montrose Fine Chemical Company Ltd	Scotland	100	Ordinary	100
Montrose Pharma Company Limited	Hungary	100	Ordinary Quota	100
Montrose Pharma UAB (iv)	Lithuania	100	Ordinary	100
Nanjing Meirui Pharma Co. Ltd	China	100	Ordinary	100
Novartis Vaccines and Diagnostics AG (vi)	Switzerland	100	Ordinary	100
Novartis Vaccines and Diagnostics Pty Ltd	Australia	100	Ordinary	100
Novartis Vaccines and Diagnostics S.L. (vi)	Spain	100	Ordinary	100
Okairos AG (iv) (vi)	Switzerland	100	Common; Preferred A; Preferred B	100
				100
Penn Labs Inc. (iv)	United States	100	Common	100
S.R. One International B.V.	Netherlands	100	Ordinary	100
S.R. One, Limited	United States	100	Units (Common)	100
Setfirst Limited	England & Wales	100	Ordinary	100
Smith Kline & French Laboratories Limited	England & Wales	100	Ordinary	100
Smith Kline & French Portuguesa-Produtos Farmaceuticos, LDA (iv)	Portugal	100	Ordinary Quota	100
SmithKline Beecham (Australia) Pty Ltd (iv) (vi)	Australia	100	Ordinary	100
SmithKline Beecham (Bangladesh) Private Limited (iv)	Bangladesh	100	Ordinary	100
SmithKline Beecham (Cork) Limited (ii)	Ireland	100	Ordinary	100
SmithKline Beecham (Export) Limited	England & Wales	100	Ordinary	100
SmithKline Beecham (H) Limited	England & Wales	100	Non-Cumulative Non-Redeemable Ordinary	100
				100
SmithKline Beecham (Investments) Limited	England & Wales	100	Ordinary	100
SmithKline Beecham (Manufacturing) Limited (ii)	Ireland	100	Ordinary	100
SmithKline Beecham (SWG) Limited	England & Wales	100	Ordinary	100
SmithKline Beecham Animal Health Company	Canada	100	Common	100
SmithKline Beecham Biologicals US Partnership	United States	100	Partnership Interests	100
SmithKline Beecham Egypt L.L.C.	Egypt	100	Quotas	100
SmithKline Beecham Farma, S.A.	Spain	100	Ordinary	100
SmithKline Beecham Holdings (Australia) Pty. Limited (iv) (vi)	Australia	100	Ordinary A; Ordinary B	100
SmithKline Beecham Inter-American Corporation (iv)	United States	100	Shares No par Value (Common)	100
SmithKline Beecham Limited	England & Wales	100	Ordinary 6.25p	100
SmithKline Beecham Marketing and Technical Services Limited	England & Wales	100	Ordinary	100
SmithKline Beecham Nominees Limited	England & Wales	100	Ordinary	100
SmithKline Beecham Overseas Limited	England & Wales	100	Ordinary	100
SmithKline Beecham Pension Plan Trustee Limited (iv)	England & Wales	100	Ordinary	100
SmithKline Beecham Pension Trustees Limited (iv)	England & Wales	100	Ordinary	100
SmithKline Beecham Pharma GmbH & Co KG	Germany	100	Partnership Capital	100
SmithKline Beecham Pharma Verwaltungs GmbH	Germany	100	Ordinary	100
SmithKline Beecham Pharmaceuticals (Pty) Limited (iv) (vi)	South Africa	100	Ordinary	100
SmithKline Beecham Pharmaceuticals Co.	United States	100	Shares No par Value (Common)	100
SmithKline Beecham Port Louis Limited (vi)	Mauritius	100	Ordinary	100
SmithKline Beecham Retirement Plan (Nominees) Pty Limited (iv) (vi)	Australia	100	Ordinary	100
SmithKline Beecham Senior Executive Pension Plan Trustee Limited (iv)	England & Wales	100	Ordinary	100
Stiefel Distributors (Ireland) Limited (ii) (iv)	Ireland	100	Ordinary	100
Stiefel Dominicana SRL (iv)	Dominican Republic	100	Ordinary Quotas	100
Stiefel Farma, S.A	Spain	100	Ordinary	100
Stiefel GmbH & Co. KG	Germany	100	Partnership Capital	100
Stiefel India Private Limited	India	100	Equity	100
Stiefel Laboratories (Ireland) Limited (ii)	Ireland	100	Ordinary	100
Stiefel Laboratories (Maidenhead) Ltd	England & Wales	100	Ordinary	100
Stiefel Laboratories (Thailand) Ltd. (Liquidated 25 Jan 2016)	Thailand	100	Ordinary; Preference	100
Stiefel Laboratories (U.K.) Ltd	England & Wales	100	Ordinary	100
Stiefel Laboratories Limited (iv)	England & Wales	100	Ordinary	100

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<b>Wholly owned subsidiaries continued</b>				
Stiefel Laboratories Pte Limited	Singapore	100	Ordinary	100
Stiefel Laboratories Pty Ltd (iv) (vi)	Australia	100	Ordinary	100
Stiefel Laboratories SA (Pty) Ltd (iv) (vi)	South Africa	100	Ordinary	100
Stiefel Laboratories Taiwan Ltd (Liquidated 5 Jan 2016)	Taiwan	100	Ordinary	100
Stiefel Laboratories, Inc.	United States	100	Common	100
Stiefel Maroc SARL	Morocco	100	Ordinary	100
Stiefel Polska SP Z O.O. w likwidacji (In liquidation)	Poland	100	Ordinary	100
Stiefel Research (Australia) Holdings Pty Ltd (iv)	Australia	100	Ordinary	100
Stiefel Research Australia Pty Ltd	Australia	100	Ordinary	100
Stiefel Research Institute, Inc. (vi)	United States	100	Common	100
Stiefel Sales, Inc. (iv) (vi)	United States	100	Common	100
Stiefel West Coast LLC	United States	100	LLC Interests	100
Strebor Inc.	United States	100	USD 1 par value (Common)	100
Tempero Pharmaceuticals, Inc.	United States	100	Series A Preference	100
			Series B Preference; Common	100
The Sydney Ross Co. (iv)	United States	100	Ordinary	100
The Wellcome Foundation Limited	England & Wales	100	Ordinary	100
UCB Pharma (Thailand) Ltd (Liquidated 25 Jan 2016)	Thailand	100	Ordinary	100
UCB Pharma Asia Pacific Sdn Bhd (iv)	Malaysia	100	Ordinary	100
Webderm, Inc. (iv) (vi)	United States	100	Common	100
Wellcome Consumer Healthcare Limited (iv)	England & Wales	100	Ordinary	100
Wellcome Consumer Products Limited (iv)	England & Wales	100	Ordinary	100
Wellcome Developments Pty Ltd (iv) (vi)	Australia	100	Ordinary	100
Wellcome Limited	England & Wales	100	Ordinary	100
Wellcome Operations Pty Ltd (iv) (vi)	Australia	100	Ordinary	100
<b>Subsidiaries where the effective interest is less than 100%</b>				
Amoun Pharmaceutical Industries Co. S.A.E.	Egypt	99.5	New Monetary Shares	99.5
Beecham Enterprises Inc. (iv)	United States	55.9	Common	100
Block Drug Company, Inc.	United States	63.5	Common	100
British Pharma Group Limited	England & Wales	50	Capital	50
Block Drug Corporation (iv)	United States	63.5	Common No Par Value	100
de Miclén a.s.	Slovakia	63.5	Ordinary	100
Duncan Consumer Healthcare Philippines Inc	Philippines	63.5	Common	100
Ex-Lax, Inc.	Puerto Rico	63.5	Common	100
Fondation Novartis Consumer Health Pour l'Avancement Des Sciences Medicales, Biologiques Et Pharmaceutiques	Switzerland	63.5	Capital	63.5
Glaxo Saudi Arabia Limited	Saudi Arabia	49	Ordinary	49
GlaxoSmithKline (Tianjin) Co. Ltd	China	90	Ordinary	90
GlaxoSmithKline Bangladesh Limited	Bangladesh	82	Ordinary	82
GlaxoSmithKline Brasil Produtos para Consumo e Saude Ltda	Brazil	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare (China) Co. Ltd	China	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare (Hong Kong) Limited	Hong Kong	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare (Ireland) Limited (ii)	Ireland	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare (Overseas) Limited	England & Wales	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare (Thailand) Limited	Thailand	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare (UK) IP Limited	England & Wales	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare (UK) Trading Limited	England & Wales	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare (US) IP LLC	United States	63.5	LLC Interests	100
GlaxoSmithKline Consumer Healthcare A/S	Denmark	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare AB	Sweden	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare AG	Switzerland	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare Argentina S.A. (iv)	Argentina	63.5	Nominative non endorseable Ordinary	100
GlaxoSmithKline Consumer Healthcare Australia Pty Ltd	Australia	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare B.V.	Netherlands	63.5	Ordinary A	100
GlaxoSmithKline Consumer Healthcare Canada Corp	Canada	63.5	Common	100
GlaxoSmithKline Consumer Healthcare Colombia SAS	Colombia	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare Czech Republic s.r.o.	Czech Republic	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare Finance Limited	England & Wales	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare Finland Oy	Finland	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare GmbH	Austria	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare GmbH & Co. KG	Germany	63.5	Partnership Capital	100

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<b>Subsidiaries where the effective interest is less than 100% continued</b>				
GlaxoSmithKline Consumer Healthcare Greece Societe Anonyme	Greece	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC	United States	63.5	LLC Interests	100
GlaxoSmithKline Consumer Healthcare Holdings Limited	England & Wales	63.5	Ordinary A Ordinary B	100 0
GlaxoSmithKline Consumer Healthcare Inc.	Canada	63.5	Common Preferred	100 100
GlaxoSmithKline Consumer Healthcare Investments (Ireland) (No 2) (ii) (v)	Ireland	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare Investments (Ireland) (No 3) Limited (ii) (v)	Ireland	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare Japan K.K.	Japan	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare Korea Co., Ltd.	Korea	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare L.L.C.	United States	63.5	LLC Interests	100
GlaxoSmithKline Consumer Healthcare Limited	India	72.5	Equity	72.5
GlaxoSmithKline Consumer Healthcare Mexico, S. De R.L. de C.V.	Mexico	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare New Zealand Limited	New Zealand	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare Norway AS	Norway	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare Philippines Inc	Philippines	63.5	Common	100
GlaxoSmithKline Consumer Healthcare Pte. Ltd.	Singapore	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare S.A.	Belgium	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare S.A.	Spain	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare S.p.A.	Italy	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare Sdn. Bhd.	Malaysia	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare Slovakia s. r. o.	Slovakia	63.5	Ownership Interest	100
GlaxoSmithKline Consumer Healthcare South Africa Pty (Ltd)	South Africa	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare Sp.z.o.o.	Poland	63.5	Common	100
GlaxoSmithKline Consumer Healthcare SRL	Romania	63.5	Ordinary	100
GlaxoSmithKline Consumer Healthcare, L.P.	United States	55.9	Partnership Interest	55.9
GlaxoSmithKline Consumer Healthcare, Produtos para a Saude e Higiene, Lda	Portugal	63.5	Ordinary Quota	100
GlaxoSmithKline Consumer Nigeria plc (iii)	Nigeria	46.4	Ordinary	46.4
GlaxoSmithKline Consumer Private Limited	India	63.5	Equity	100
GlaxoSmithKline Consumer Trading Services Limited	England & Wales	63.5	Ordinary	100
GlaxoSmithKline Costa Rica S.A.	Costa Rica	63.5	Ordinary	100
GlaxoSmithKline Dungarvan Limited (ii)	Ireland	63.5	Ordinary	100
GlaxoSmithKline Healthcare AO	Russia	63.5	Ordinary	100
GlaxoSmithKline Healthcare GmbH	Germany	63.5	Ordinary	100
GlaxoSmithKline Healthcare Ukraine O.O.O.	Ukraine	63.5	Ownership Interest	100
GlaxoSmithKline Landholding Company, Inc	Philippines	39.9	Common	100
GlaxoSmithKline Limited	Kenya	63.5	Ordinary	100
GlaxoSmithKline OTC (PVT.) Limited	Pakistan	63.5	Ordinary	100
GlaxoSmithKline Pakistan Limited	Pakistan	82.6	Ordinary	82.6
GlaxoSmithKline Panama S.A.	Panama	63.5	Ordinary	100
GlaxoSmithKline Paraguay S.A.	Paraguay	63.5	Ordinary	100
GlaxoSmithKline Pharmaceuticals Limited	India	75	Equity	75
GlaxoSmithKline S.A.E.	Egypt	91.2	Ordinary	91.2
GlaxoSmithKline Sante Grand Public SAS	France	63.5	Ordinary	100
GlaxoSmithKline Tuketici Sagligi Anonim Sirketi	Turkey	63.5	Nominative	100
GlaxoSmithKline-Consumer Hungary Limited Liability Company	Hungary	63.5	Membership	100
GSK Consumer Healthcare Singapore Pte. Ltd	Singapore	63.5	Ordinary	100
Iodosan S.p.A.	Italy	63.5	Ordinary	100
Kuhs GmbH	Germany	63.5	Equity	100
Laboratorios Viiv Healthcare, S.L.	Spain	78.3	Ordinary	100
Modern Pharma Trading Company L.L.C.	Egypt	98.2	Quotas	98.2
Novartis Consumer Health Australasia Pty Ltd	Australia	63.5	Ordinary Redeemable Preference	100 100
Novartis Consumer Health Canada Inc./Novartis Sante Familiale Canada, Inc.	Canada	63.5	Common	100
Novartis Consumer Health GmbH	Germany	38.1	Ordinary	100
Novartis Consumer Health LLC	Russia	63.5	Participation Interest	100

## Group companies continued

Name	Country of incorporation	Effective % Ownership	Security	% Held by Class of Share
<b>Subsidiaries where the effective interest is less than 100% continued</b>				
Novartis Consumer Health N.V.	Belgium	63.5	Ordinary	100
Novartis Consumer Health S.A.	Spain	63.5	Ordinary	100
Novartis Consumer Health S.A.	Switzerland	63.5	Ordinary	100
Novartis Consumer Health Schweiz AG	Switzerland	63.5	Ordinary	100
Novartis Consumer Health Services S.A.	Switzerland	63.5	Registered Shares	100
Novartis Consumer Health UK Limited	England & Wales	63.5	Ordinary	100
Novartis Consumer Health, Inc.	United States	63.5	Common	100
Novartis Consumer Health-Gebro GmbH	Austria	38.1	Ordinary	60
Novartis Sante Familiale S.A.S. (In liquidation)	France	63.5	Ordinary	100
P.T. SmithKline Beecham Pharmaceuticals	Indonesia	99	A Shares	100
			B Shares	100
P.T. Sterling Products Indonesia	Indonesia	63.5	A Shares	100
			B Shares	100
Panadol GmbH	Germany	63.5	Ordinary	100
PHIVCO Jersey II Limited (iv) (v)	Jersey	78.3	Ordinary	100
PHIVCO Jersey Limited (iv) (v)	Jersey	78.3	Ordinary	100
PHIVCO UK II Limited	England & Wales	78.3	Ordinary	100
PHIVCO UK Limited	England & Wales	78.3	Ordinary	100
PHIVCO-1 LLC	United States	78.3	LLC Interests	100
PHIVCO-2 LLC	United States	78.3	LLC Interests	100
PT Glaxo Wellcome Indonesia	Indonesia	95	A Shares	100
			B Shares	100
PT. Bina Dentalindo (In liquidation)	Indonesia	63.5	Ordinary	100
Shionogi-ViiV Healthcare LLC (iv)	United States	78.3	Common Interests	100
Sino-American Tianjin Smith Kline & French Laboratories Ltd	China	34.9	Ordinary	55
SmithKline Beecham (Private) Limited	Sri Lanka	99.6	Ordinary	99.6
SmithKline Beecham Research Limited	England & Wales	63.5	Ordinary	100
SmithKline Beecham S.A.	Spain	63.5	Ordinary	100
SmithKline Beecham-Biomed O.O.O.	Russia	97	Participation Interest	97
Stafford-Miller (Ireland) Limited (ii)	Ireland	63.5	Ordinary	100
Stafford-Miller Limited	England & Wales	63.5	Ordinary	100
			Non-Cumulative Non Redeemable Preference	100
Sterling Drug (Malaya) Sdn Berhad	Malaysia	63.5	Ordinary	100
Sterling Products International, Incorporated (iv)	United States	63.5	Common	100
Stiefel Consumer Healthcare (UK) Limited	England & Wales	63.5	Ordinary	100
Stiefel Egypt LLC (iv)	Egypt	99	Quota	99
Stiefel Manufacturing (Ireland) Limited (ii)	Ireland	63.5	Ordinary	100
ViiV Healthcare (South Africa) (Proprietary) Limited	South Africa	78.3	Ordinary	100
ViiV Healthcare BV	Netherlands	78.3	Ordinary	100
ViiV Healthcare Company	United States	78.3	Common	100
ViiV Healthcare Finance 1 Limited (iv)	England & Wales	78.3	Ordinary	100
ViiV Healthcare Finance 2 Limited (iv)	England & Wales	78.3	Ordinary	100
ViiV Healthcare GmbH	Germany	78.3	Ordinary	100
ViiV Healthcare GmbH	Switzerland	78.3	Ordinary	100
ViiV Healthcare Kabushiki Kaisha	Japan	78.3	Ordinary	100
ViiV Healthcare Limited	England & Wales	78.3	Class A Shares	100
			Class B Shares	0
			Class C Shares	0
			Class D1 Preference	0
			Class D2 Ordinary	0
ViiV Healthcare Overseas Limited	England & Wales	78.3	Ordinary	100
ViiV Healthcare Pty Ltd	Australia	78.3	Ordinary	100
ViiV Healthcare Puerto Rico, LLC	Puerto Rico	78.3	LLC Interests	100
ViiV Healthcare S.r.l.	Italy	78.3	Quota	100
ViiV Healthcare SAS	France	78.3	Ordinary	100
ViiV Healthcare sprl	Belgium	78.3	Ordinary	100
ViiV Healthcare Trading LLC	Russia	78.3	Participation Interest	100
ViiV Healthcare Trading Services UK Limited	England & Wales	78.3	Ordinary	100
ViiV Healthcare UK (No.2) Limited (v)	Jersey	78.3	Ordinary	100
ViiV Healthcare UK (No.3) Limited	England & Wales	78.3	Ordinary	100
ViiV Healthcare UK (No.4) Limited (iv)	England & Wales	78.3	Ordinary	100
ViiV Healthcare UK Limited	England & Wales	78.3	Ordinary	100

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## continued

### Group companies continued

Name	Country of incorporation	Effective % Ownership	Security	% Held by Class of Share
<b>Subsidiaries where the effective interest is less than 100% continued</b>				
ViiV Healthcare ULC	Canada	78.3	Common	100
ViiV Healthcare Venture LLC	United States	78.3	LLC Interests	100
ViiV HIV Healthcare Unipessoal Lda	Portugal	78.3	Quota	100
Winster Pharmaceuticals Limited	Nigeria	46.4	Ordinary	100
Zhejiang Tianyuan Bio-Pharmaceutical Co. Ltd	China	95	Ordinary	95
<b>Associates</b>				
Calci Medica Inc.	United States	33.9	Series A and Junior Preferred	33.9
Index Ventures Life VI (Jersey) LP	United States	25	Partnership Interest	25
Theravance, Inc. (now Innoviva, Inc.)	United States	27.8	Common	27.8
JCR Pharmaceuticals Co. Ltd	Japan	24.6	Common	24.6
Kurma Biofund II, FCPR	France	32	Partnership Interest	32
Longwood Founders Fund LP	United States	28	Partnership Interest	28
River Vision Development Corp.	United States	33	Series A Preferred	33
<b>Joint Ventures</b>				
Chiron Panacea Vaccines Private Ltd (In liquidation)	India	50		
Japan Vaccine Co., Ltd	Japan	50		
Japan Vaccine Distribution Co., Ltd	Japan	50		
Qualivax Pte Limited	Singapore	50		
Qura Therapeutics LLC	United States	50		

### Key

- (i) Directly owned by GlaxoSmithKline plc.
- (ii) Exempt from the provisions of section 347 and 348 of the Companies Act 2014 (Ireland), in accordance with the exemptions noted in Section 357 of that Act.
- (iii) Consolidated as a subsidiary in accordance with section 1162 (4)(a) of the Companies Act 2006 on the grounds of dominant influence.
- (iv) Dormant company.
- (v) Tax resident in the UK.
- (vi) Entity expected to be disposed of or removed in 2016.

## **Exhibit D**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

---

PETER HUMPHREY, YU YINGZENG, and  
CHINAWHYS COMPANY LTD,

Plaintiffs,

v.

GLAXOSMITHKLINE PLC and  
GLAXOSMITHKLINE LLC,

Defendants.

---

Civil Action No.: 2:16-CV-5924

**DECLARATION OF PETER HUMPHREY**

I, Peter Humphrey, being over 18 years of age and competent to make this declaration,  
hereby declare that:

1. I make this declaration in support of Plaintiffs' Opposition to Defendants' Motion  
to Compel Arbitration.

2. Following our release from prison in June 2015, I was deported from China and  
am banned from entering China for a period of ten years, and therefore will not be able to enter  
China until at least 2025.

3. My wife Yu Yingzeng would almost certainly not be granted a visa to enter China  
if she applied for one.

4. Even if we were legally able to enter China, we would not be able to do so  
because of personal safety issues.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: March 2, 2017

A handwritten signature in black ink, appearing to read "P. Humphrey", followed by a long, sweeping horizontal stroke that extends to the right.

Peter Humphrey

## **Exhibit E**



Menu

## Global compliance

The Global Compliance function is responsible for supporting the development and implementation of practices that facilitate employees' compliance with laws and Group policy.

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Registered office: 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom.

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## Overview

The thrust of our compliance efforts is the promotion of ethical behaviour and corporate responsibility in accordance with our values and due diligence in preventing and detecting misconduct or non-compliance with laws or regulations, supported by effective compliance systems.

Our employees are encouraged to seek help and to report concerns or suspected cases of misconduct without the fear of retaliation. Employees can do this through line management or confidentially through our Speak Up Integrity reporting channels. All concerns and allegations are fairly and independently investigated and disciplinary action, if applicable, is commensurate with the issues presented.

The Global Compliance organisation comprises three groups:

Global Compliance Business Partners, who are aligned to each business unit. Their role is to proactively partner with senior leaders to drive a values and compliance-based culture and improve risk identification and management practices;

Global Compliance Operations centrally manages our compliance activities (e.g. analytics, reporting, communications, policy administration, project management and training), with a focus on efficiency, consistency and continuous improvement;

Global Compliance Investigations co-ordinates all compliance-related investigations, ensuring consistency and efficiency of investigations across geographies and business units.

Global Compliance contact information	
Global Compliance Business Partners	Contact Details
Nick Hirons - SVP, Governance, Ethics & Assurance	Email: Nick.J.Hirons@gsk.com  UK Phone: +44 (0) 20 8047 4501
Sean Roberts - SVP Legal Ops & Compliance Officer - Consumer Healthcare	Email: Sean.J.Roberts@gsk.com  US Phone: + 44 (0) 20 8047 4614
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Global Compliance Business Partners	Contact Details
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Michael Shaw – VP Compliance Officer - North America Pharmaceuticals	Email: Michael.L.Shaw@gsk.com  US Phone: + 1-215-751-7337

## Speak Up Integrity lines

Global Ethics & Compliance oversees the [GSK Speak Up Integrity Lines](#) through which alleged breaches of legal or regulatory obligations, financial fraud (including accounting internal controls and auditing), or any other alleged contravention of [GSK's Code of Conduct \(PDF\)](#) and company policies can be reported using different communication channels. Concerns may be reported anonymously if desired.

A secure, offsite post office box may also be used:

Mailing Address:

Box 58572

Philadelphia

Pennsylvania 19102

USA

Please do not use the Speak Up Integrity Lines or post office box above for product enquiries or to report adverse events. Visit the [contact us page](#) for instructions on where to submit questions on these matters.

## GSK's Code of Conduct

[GSK's Code of Conduct \(PDF\)](#) is the foundation for all the company policies. It sets out the fundamental principles that the company values and that employees should apply in their daily work. Supporting the Code of Conduct policy is a range of corporate policies providing specific guidance in areas such as competition law, marketing practices, non-discrimination, share dealing, and conflicts of interest. GSK's employee guide to business conduct highlights the Code of Conduct, core compliance policies and provides guidance to employees. It is the responsibility of each employee to implement the code and follow the employee guide to sustain the trust and confidence of all GSK stakeholders.

## GSK Code of Conduct translations (PDFs)

[Arabic](#)

[Brazilian-Portuguese](#)

Chinese

Czech

French

German

Hindi

Hungarian

Indonesian

Italian

Japanese

Korea

Malay

Polish

Portuguese-EU

Romanian

Russian

Spanish-EU

Thai

Traditional Chinese

Turkish

Urdu

Vietnamese

## GSK's Public Policy Statement on Working with Third Parties

At GlaxoSmithKline (GSK), we are committed to operating to the highest ethical standards to help maximise the long term sustainability of our business and of the communities in which we operate. We aim to comply with all laws, rules and regulations governing our activities and, in addition, have developed a comprehensive framework of GSK policies, guidelines and standard operating procedures to help drive high ethical standards.

We strive to conduct business with third parties including suppliers, distributors, equity stake holdings and other business partners (collectively, "Third Parties") who share our commitment to high ethical standards and operate in a responsible way.

As such, [GSK's public policy statement on working with third parties \(PDF\)](#) sets out our expectation that Third Parties will:

Share our commitment to high ethical standards

Comply with all applicable laws and regulations and adopt, at a minimum, GSK's Anti-Bribery & Corruption and Labour Rights Principles

Where relevant, comply with our standards on quality, patient safety, health and safety and the environment

Create a culture which supports staff reporting of suspected violations of law, rules and regulations, as well as of unethical conduct, without fear of reprisal or retaliation.

Third Parties should also reference our general terms and conditions on our [procurement page](#).



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## **Exhibit F**

**Relevant Excerpts from 2015 Annual Report of  
GlaxoSmithKline Capital plc**

**GlaxoSmithKline Capital plc**  
(Registered number: 2258699)

**Annual Report**

**for the year ended 31 December 2015**

**Registered office address:**  
980 Great West Road  
Brentford  
Middlesex  
TW8 9GS

**GlaxoSmithKline Capital plc**  
**Registered number: (2258699)**

**Strategic report for the year ended 31 December 2015**

The Directors present their strategic report on GlaxoSmithKline Capital plc (the "Company") for the year ended 31 December 2015.

**Principal activities**

The Company is a member of the GlaxoSmithKline Group of companies (the "Group") and issues notes under the Group's European and US Medium Term Note programme and provides financing and financial services to other Group entities.

The Directors do not envisage any change to the nature of the business in the foreseeable future.

**Review of business**

The Company made a profit for the financial year of £8,749k (2014: £6,734k), which will be transferred to reserves. The Directors are of the opinion that the current level of activity and the year end financial position are satisfactory and will remain so in the foreseeable future.

At 31 December 2015, the Company had in issue £7,333,954k Euro Medium Term Notes and £2,708,365k US Medium Term Notes (2014: £8,744,819k and £3,189,406k respectively) which mature at dates between 2017 and 2045. All notes currently in issue pay interest on a fixed rate basis.

During the year, two bonds that were issued under the Group's European and US Medium Term Note programmes matured during the year; they were the 3.875% €1.6 billion European Medium Term Note in July 2015 and the 0.75% US\$1 billion US Medium Term Note in May 2015.

*Principal risks and uncertainties*

The Directors of GlaxoSmithKline plc manage the risks of the Group at a group level, rather than at an individual business unit level. For this reason, the Company's Directors believe that a discussion of the Group's risks would not be appropriate for an understanding of the development, performance or position of the Company's business. The principal risks and uncertainties of the Group, which include those of the Company, are discussed in the Group's 2015 Annual Report which does not form part of this report.

*Key Performance Indicators (KPIs)*

The Directors of the Group manage the Group's operations on a business sector basis. For this reason, the Company's directors believe that analysis using key performance indicators for the Company is not necessary or appropriate for an understanding of the development, performance or position of the Company's business. The development, performance and position of the Group are discussed in the Group's 2015 Annual Report which does not form part of this report.

**First time adoption of FRS 101**

In the current year, the company has adopted Financial Reporting Standard 100 "Application of Financial Reporting Requirements" ("FRS 100") and Financial Reporting Standard 101 "Reduced Disclosure Framework" ("FRS 101"). In previous years, the financial statements were prepared in accordance with applicable UK accounting standards. This change in the basis of preparation has not materially altered the recognition and measurement requirements previously applied in accordance with applicable accounting standards.

On behalf of the Board

**A Walker**  
**For and on behalf of Glaxo Group Limited**  
**Corporate Director**  
26 April 2016

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

PETER HUMPHREY, YU YINGZENG, and  
CHINAWHYS COMPANY LTD,

Plaintiffs,

v.

GLAXOSMITHKLINE PLC and  
GLAXOSMITHKLINE LLC,

Defendants.

Civil Action No.: 2:16-CV-5924

**DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF  
THEIR MOTION TO COMPEL ARBITRATION, OR, IN THE  
ALTERNATIVE, MOTION TO DISMISS THE COMPLAINT**

Defendants GlaxoSmithKline PLC (“**GSK PLC**”) and GlaxoSmithKline LLC (“**GSK LLC**”) (collectively, “**GSK Defendants**”), through their counsel, submit the following reply memorandum in further support of their motion to compel arbitration, or in the alternative, motion to dismiss the complaint for lack of personal jurisdiction, failure to state a claim upon which relief can be granted, failure to join an indispensable party, and failure to bring a timely action under Pennsylvania law.

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## I. INTRODUCTION

It is not what Plaintiffs say in their Opposition Brief that tells the story in this case, it is what they do not say. Despite expending pages and pages in an attempt to cast themselves as victims of a global conspiracy, they fail to substantiate those conclusory statements with plausible facts. Most importantly, they fail to dispute, indeed address, threshold issues that resolve this matter by mandating its arbitration. Those include the following:

- Plaintiffs do not dispute that they negotiated, executed and implemented the Consultancy Agreement.
- Plaintiffs do not dispute the validity or enforceability of the Consultancy Agreement.
- Plaintiffs do not dispute the validity or enforceability of the arbitration provision, or that they agreed to arbitrate all disputes in China, pursuant to Chinese law and before CIETAC.
- Plaintiffs do not dispute that all conduct alleged in the Complaint as giving rise to their injuries occurred in connection with the Consultancy Agreement.
- Plaintiffs do not dispute that the Consultancy Agreement was executed by GSK China and Peter Humphrey on behalf of ChinaWhys.
- Plaintiffs do not dispute that they each (ChinaWhys, Humphrey and Yu) acted on and performed services in implementation of the Agreement.

These undisputed facts should lead this Court to the undeniable conclusion that this lawsuit is not properly before it. In addition, Plaintiffs have failed to join GSK China, the only entity with which they interacted, and the only entity that could possibly have made the alleged misrepresentations upon which Plaintiffs base their claims. To the extent Plaintiffs might have any cognizable claim (which the GSK Defendants dispute), it would be against GSK China. Plaintiffs do not claim that GSK China acted as the alter ego or agent of GSK PLC or GSK LLC, and GSK China's actions cannot be imputed to the GSK Defendants.

Even on the merits, Plaintiffs have failed to establish that GSK PLC maintains sufficient contacts with the United States to give rise to jurisdiction, or to allege fundamental facts necessary to support their RICO or state law claims. Despite their strictly conclusory claim of a conspiratorial web, the Complaint does not allege a single fact showing that the conduct for which Plaintiffs were prosecuted by Chinese authorities was directed by or performed at the request of GSK PLC or GSK LLC—or even that those entities knew of Plaintiffs’ investigation. Absent such allegations, Plaintiffs cannot state claims against the GSK Defendants that are “plausible on [their] face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2007); *see also Bell Atl. Co. v. Twombly*, 550 U.S. 544, 556 (2007). The matter should be referred to arbitration, or, in the alternative, their Complaint dismissed with prejudice.

## II. ARGUMENT

The Complaint provides the legal framework for Plaintiffs’ case. To the extent Plaintiffs set forth additional facts in their Opposition Brief, the Court should disregard them for purposes of the motion to compel arbitration and to dismiss under Federal Rule of Civil Procedure 12(b)(6). *Pennsylvania ex rel. Zimmerman v. PepsiCo*, 836 F.2d 173, 181 (3d Cir. 1988).

### A. **GSK PLC And GSK LLC Have A Right To Enforce The Arbitration Provisions Of The Consultancy Agreement, Which Is Binding On Humphrey, Yu, And ChinaWhys.**

“When parties agree to arbitrate, they agree to do so ‘through to completion’ ....” *Adorra Servs. Inc. v. Venfleet, Ltd.*, 355 F. App’x 622, 625 (3d Cir. 2009) (quoting *Dluhos v. Strasberg*, 321 F.3d 365, 369-70 (3d Cir. 2003)). Plaintiffs’ attempt to circumvent the arbitration clause in the Agreement is a fruitless effort to undo their binding contractual promise to resolve through arbitration “[a]ll disputes arising out of or in connection with th[e] Agreement.” (See Ex. 1 to Mot. to Compel (Doc. 19-5) § 11.) Plaintiffs do not dispute that the Consultancy

Agreement is a valid binding contract or that the arbitration clause is a valid enforceable provision of that Agreement. They likewise do not dispute that the language of the arbitration clause (i.e., to arbitrate all disputes “arising out of or in connection with” the Agreement, (Ex. 1 to Mot. to Compel (Doc. 19-5) § 11)), creates a presumption of arbitrability unless Plaintiffs establish with “positive assurance” that the present dispute is not covered by the arbitration clause, *Moses H. Cone Mem. Hosp. v. Mercury Constr. Corp.*, 460 U.S. 1, 24 (1983). In fact, they do not contest that (1) the present dispute is covered by the arbitration provision; (2) they were carrying out ChinaWhys’ obligations in furtherance of that contract; (3) the Agreement is the **only** connection whatsoever between them and any GSK entity; or (4) a connection exists only between Plaintiffs and GSK China, not GSK PLC or GSK LLC.

Indeed, the alleged misrepresentation that Plaintiffs claim (without basis in fact) they received could **only** have originated with the GSK China employees who, according to the Complaint, actually interacted with Plaintiffs. The Court should therefore reject Plaintiffs’ attempts to ascribe fraud to GSK PLC or GSK LLC, and should enforce their contractual bargain with GSK China.

1. GSK PLC And GSK LLC May Invoke The Arbitration Provision Of The Consultancy Agreement Because They Have A Corporate Relationship With GSK China, The Contract Signatory, And The Dispute Is Inextricably Intertwined With That Agreement.

Plaintiffs implausibly suggest that GSK PLC and GSK LLC cannot invoke the arbitration clause of the Agreement because they are not signatories to it. (*See* Opp’n Br. (Doc. 23), at 17-19.) That argument rests on legal misinterpretations, impermissible pleading practice, and indifference to the facts of the case.

Contrary to Plaintiffs’ claim that invocation of an arbitration clause by a non-signatory is “novel,” (*see id.* at 16), courts have held that a non-signatory may enforce an arbitration clause

when (1) “the claims were intimately founded in and intertwined with the underlying contract obligations,” and (2) the non-signatory has a “close relationship” with a signatory.<sup>1</sup> *E.I. DuPont de Nemours & Co. v. Rhone Poulenc Fiber & Resin Intermediaries, S.A.S.*, 269 F.3d 187, 199 (3d Cir. 2001); *accord Bannet v. Hankin*, 331 F. Supp. 2d 354, 359-60 (E.D. Pa. 2004) (allowing non-signatory to enforce an arbitration clause because it was affiliated with the signatory entity, and the plaintiff had chosen not to join the signatory entity in “an attempt to make an end-run around the arbitration clause”). Both elements are met here.

First, the present dispute was intimately founded in and is “intertwined with” the Agreement because it arises out of services Plaintiffs provided to GSK China pursuant to the Agreement. *Id.* Notably, all of Plaintiffs’ interactions with any GSK entity stem entirely and solely from the Agreement, and the only communications that Plaintiffs described in the Complaint were with GSK China or China-based personnel responsible for the Agreement. The Complaint concedes these points:

- Plaintiffs were retained to conduct an investigation into a GSK China employee, to be conducted entirely in China, with reports made to GSK China personnel, (see Compl. (Doc. 1) ¶¶ 51, 70);
- The only individuals from any GSK entity with whom Plaintiffs ever allegedly met were “Mark Reilly, CEO of GSK (China) Investment Co., April Zhao, Legal Counsel of GSK China, and Brian Cahill, also legal counsel,” (*id.* ¶ 50), none of whom were (or are alleged to have been) employed by GSK PLC or GSK LLC;
- Reilly, Zhao, and Cahill are the only individuals whom the Complaint alleges made any representation to Plaintiffs that was purportedly false, (*id.* ¶ 53);
- All of Plaintiffs’ claims are predicated on alleged “false information supplied” by Reilly, Zhao, and Cahill, (*id.* ¶ 63; *see also id.* ¶ 59); and

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<sup>1</sup> Plaintiffs’ argument that *Invista S.A.R.L. v. Rhodia, S.A.*, 625 F.3d 75, 85 (3d Cir. 2010), compels a different result is misplaced. In that case, the court did not rule on the question of whether the parties were bound by the arbitration clause because the court found it lacked personal jurisdiction over the defendant and subject matter jurisdiction over the appeal. *Id.* at 87-88. The court did not address enforcement of the arbitration clause against the non-signatories.

- ChinaWhys submitted the scope of work attached to the Agreement to Mark Reilly as “Chairman” of “GlaxoSmithKline (China) Investment Co. Ltd.”<sup>2</sup> (See Ex. 1 to Mot. to Compel (Doc. 19-5), at 14.)

Nowhere in the Complaint do Plaintiffs allege interactions with individuals from GSK PLC or GSK LLC. To the contrary, their Agreement with GSK China is the *sine qua non* without which Plaintiffs’ alleged injuries would not exist, and the only purported misrepresentations upon which their fraud claims could be based are those allegedly made by GSK China personnel. Thus, the issues which non-signatories GSK PLC and GSK LLC want “to resolve are intertwined with the agreement that the signatory signed.” *Heller v. Deutsche Bank AG*, No. 04-3571, 2005 WL 665052, at \*5 (E.D. Pa. Mar. 17, 2005).

Second, GSK PLC and GSK LLC are entitled to invoke the arbitration clause of the Agreement, because they are members of the same corporate family as GSK China. GSK PLC is the indirect parent company of GSK China, and GSK LLC is a sister corporation within a common ownership structure. This relationship among the GSK Defendants and GSK China, the entity that executed the Agreement, supports enforcement of the Agreement’s arbitration clause. See *E.I. DuPont*, 269 F.3d at 199 (allowing enforcement of arbitration clauses by non-signatories based on a “close relationship” with the entity that signed the contract).

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<sup>2</sup> Ordinarily, a motion to compel arbitration can be resolved on the face of the complaint, in which case the court should apply a Rule 12(b)(6) standard of review. *Guidotti v. Legal Helpers Debt Resolution LLC*, 716 F.3d 764, 775 (3d Cir. 2013). When the motion cannot be resolved on the face of the complaint and the documents integral to it, the court may allow the parties to submit evidence outside the complaint, and address the motion under the summary judgment standard. *Id.* Here, the Court should apply the Rule 12(b)(6) standard, and rule on the motion based on the face of the Complaint and the Consultancy Agreement. Although Plaintiffs did not attach that Agreement to their pleading, they acknowledge that they were retained to provide investigation services in connection with this case, and that retention occurred pursuant to the Agreement. (See, e.g. Compl. (Doc. 1) ¶¶ 61-63.) The Agreement, as the operative contract of retention, is therefore “integral to” their Complaint, and the Court may consider it under the Rule 12(b)(6) standard. *U.S. Express Lines Ltd. v. Higgins*, 281 F.3d 383, 388 (3d Cir. 2002), *superseded on other grounds as explained in Langman v. Keystone Nazareth Bank & Trust Co.*, 502 F. App’x 220, 225 n.3 (3d Cir. 2012).

2. The Court Should Enforce The Arbitration Provision Of The Consultancy Agreement Against Plaintiffs Because They Were Acting On ChinaWhys' Behalf At All Times Relevant To The Complaint.

Contrary to the plain language of the Agreement as well as their own Complaint, Plaintiffs suggest that “there is no evidence that [they] agreed to arbitrate anything” and that they never “manifested an intent *to arbitrate*,” (See Opp’n Br. (Doc. 23), at 20, 22.). That is pure fiction. The Agreement did not spring out of the ether without the active knowledge and participation of the Plaintiffs. All three plaintiffs—including Humphrey as *the signatory* to the Agreement on behalf of ChinaWhys and Yu as an acknowledged full partner and participant in the work executed under that agreement—intimately participated in its negotiation, execution, and implementation. (See Compl. (Doc. 1) ¶¶ 49-63.)

The Complaint alleges that Humphrey and Yu met with Reilly, Zhao, and Cahill on April 15, 2013 to discuss retention of ChinaWhys by GSK China to investigate a GSK China employee. (See *id.* ¶¶ 49-52.) On April 21, 2013, Humphrey submitted a project proposal to Reilly, which Humphrey stated was “further to the recent contacts between yourself **and ChinaWhys Co Ltd**,” the plaintiff -entity named in this case. (See Ex. 1 to Mot. to Compel (Doc. 19-5), at 14.) Only five days later (on April 26, 2013), Humphrey executed the Agreement, which incorporated his proposal as an integrated addendum to the contract. (*Id.*)

The Complaint describes in detail Humphrey and Yu’s efforts to investigate a GSK China employee—the same investigation described in Humphrey’s proposed scope of work, which was incorporated into the Agreement. (Compare Compl. (Doc. 1) ¶¶ 63-70, with Ex. 1 to Mot. to Compel (Doc. 19-5), at 16-18.) The Complaint also describes the services and work performed by plaintiffs Humphrey, Yu, and ChinaWhys in furtherance of that Agreement, (see, e.g., Compl. (Doc. 1) ¶¶ 63, 65, 128(c)), including an investigation and preparation of an “Investigation

Report ... on Shi,” (*id.* ¶ 70), which was produced by ChinaWhys Company Limited, the same entity that is named as a Plaintiff in the Complaint.

i. *The Court Should Compel Plaintiff Chinawhys To Arbitrate Under The Consultancy Agreement.*

Plaintiffs ignore entirely the relationship of the ChinaWhys entities as it relates to the Consultancy Agreement. It is as if they ask the Court to believe that the Agreement was signed by an entity to which they have no relationship. The allegations of their Complaint demonstrate otherwise, and principles of alter ego, agency, and assumption of contract rights each individually bind ChinaWhys to the Agreement. Plaintiffs claim that the “Complaint does not establish ... alter ego factors” as to ChinaWhys. (*See* Opp’n Br. (Doc. 23), at 21.) That argument fails, as Plaintiffs’ own pleading and documents integral to and referenced in it establish that, although ChinaWhys (Shanghai) Consulting Co. Ltd appears (via Humphreys signature) as the signatory to the Agreement, ChinaWhys Company Ltd. (the named Plaintiff) carried out its contractual obligations. The project proposal referred to those entities interchangeably, (*see* Ex. 1 to Mot. to Compel (Doc. 19-5), at 14). The Complaint attributes the investigation of Shi to ChinaWhys Company Ltd (and to Humphrey and Yu acting on its behalf) regardless of the name of the entity on whose behalf Humphreys signed the Agreement. (*See* Compl. (Doc. 1) ¶¶ 63, 65, 128(c).) As Plaintiffs allege, that investigation produced ChinaWhys’ Investigation Report, (*id.* ¶ 70), in satisfaction of ChinaWhys (Shanghai)’s contractual obligations. In short, the ChinaWhys entities “simply acted interchangeably and in disregard of their corporate separateness,” and they thus constitute alter egos of one another for purposes of enforcing the Agreement’s arbitration clause. *Publicker Indus., Inc. v. Roman Ceramics Corp.*, 603 F.2d 1065, 1070 (3d Cir. 1979).

ChinaWhys was also acting as ChinaWhys (Shanghai)'s agent to execute its contractual obligations, a fact that Plaintiffs do not and cannot dispute. Instead, they suggest that "agency principles cannot be used to require non-signatories to arbitrate." That is a misstatement of law. Contrary to Plaintiff's arguments, the United States Court of Appeals for the Third Circuit has held that "[a]gency logic has been applied to bind non-signatory business entities to arbitration agreements." *Pritzker v. Merrill Lynch, Pierce, Fenner & Smith*, 7 F.3d 1110, 1122 (3d Cir. 1993).

As to assumption of contract, the pertinent point is not merely that ChinaWhys personnel (Humphrey, Yu, and other employees) were involved in carrying out the Agreement, (*see* Opp'n Br. (Doc. 23), at 21-22), but that, even absent an alter ego or agency relationship, they only did so because ChinaWhys expressly or impliedly assented to and agreed to be bound by ChinaWhys (Shanghai)'s contract. A contrary finding would implausibly mean that ChinaWhys provided its personnel to ChinaWhys (Shanghai) on a completely gratuitous basis with no purpose or intent to satisfy the requirements of the Agreement. ChinaWhys was not required to expressly assume the arbitration clause before it could be bound, as Plaintiffs suggest. (*Id.*) Instead, it is sufficient that ChinaWhys agreed to carry out ChinaWhys (Shanghai)'s contractual obligations, because remedial provisions of a contract follow assumption of contract rights by operation of law. *See Trippe Mfg. Co. v. Niles Audio Corp.*, 401 F.3d 529, 533 (3d Cir. 2005) (applying New York law to hold that an assumption of contract rights "cannot alter a contract's bargained-for remedial measures," including arbitration (quoting *GMAC Commercial Credit, LLC v. Springs Indus., Inc.*, 171 F. Supp. 2d 209, 26 (S.D.N.Y. 2001))). The Court should not allow Plaintiffs to play a shell game for the sole purpose of avoiding enforcement of the very Agreement that they

negotiated, executed and implemented. This Court should enforce the arbitration clause of the Agreement against ChinaWhys under principles of alter ego, agency, and assumption.

ii. *The Court Should Compel Plaintiffs Humphrey And Yu To Arbitrate Under The Agreement.*

Similar principles apply to Humphrey and Yu. Plaintiffs claim that they “are aware of no case[] holding that non-signatory plaintiffs may be compelled to arbitrate under an agency theory.” (See Opp’n Br. (Doc. 23), at 20.) That is not true, as Plaintiffs themselves cited and relied upon this Court’s decision in *Just B Method, LLC v. BSCPR, LP*, No. 14-1516, 2014 WL 5285634 (E.D. Pa. Oct. 14, 2014) (Quiñones Alejandro, J.), in which this Court compelled a non-signatory plaintiff to proceed to arbitration based on an agency theory because, like Humphrey and Yu, the plaintiff was a principal and founder of the signatory entity, exercised “guidance and control” over its actions, and signed the relevant contract on the signatory’s behalf. *Id.* at \*8.

Nor can Plaintiffs credibly claim that “there is no evidence that Humphrey or Yu agreed to arbitrate anything,” (*id.* at 20), when Humphrey’s signature appears on the Agreement and when the Complaint describes an extensive investigation by ChinaWhys, Humphrey, and Yu to execute on that very same Agreement. (See Compl. (Doc. 1) ¶¶ 49-63; Ex. 1 to Mot. to Compel. (Doc. 19-5), at 11, 19; Br. in Supp. of Mot. to Compel (Doc. 19-1), at 21.) The Complaint alleges that Humphrey and Yu are “co-founder[s]” and “employees” of ChinaWhys, (Compl. (Doc. 1) ¶¶ 6, 128(c)) and that Humphrey signed the Agreement as the “managing director” of ChinaWhys (Shanghai). (Ex. 1 to Mot. to Compel (Doc. 19-5), at 19.) Plaintiffs have not contested the existence of an agency relationship; as a result, under *Just B Method*, arbitration is proper as a matter of law.

Plaintiffs concede that an estoppel theory can allow a court to enforce an arbitration provision against a non-signatory who acts intending to benefit from the contract. (See Opp’n

Br. (Doc. 23), at 20.) They claim, however, that estoppel theory does not apply here because “they have suffered only harm” from the contract. (*Id.*) The relevant question, however, is whether the non-signatory “*sought* to reap the full benefits of the Agreement”—i.e., whether it acted *intending to benefit from the Agreement*. *Just B Method*, 2014 WL 5285634, at \*9 (emphasis added). An actual benefit is not required. Were that not the case, an arbitration clause could never be enforced against a non-signatory plaintiff under an estoppel theory because any plaintiff filing a lawsuit would claim that he or she suffered harm rather than received a benefit under a contract. By acknowledging that Plaintiffs Humphrey and Yu acted for the purpose of discharging the obligations of the Agreement and obtaining payment for those services, (*see* Opp’n Br. (Doc. 23), at 21-22), Plaintiffs have conceded the propriety of arbitration.

That concession underscores a fundamental disconnect that runs throughout Plaintiffs’ arguments here. On the one hand, they suggest that they were victims of misrepresentations and fraud perpetrated in the course of their retention by GSK China. On the other, they claim that they are not signatories to the Consultancy Agreement, which is the sole source of that retention and the reason for any such relationship. Again, this is little more than an artifice designed to circumvent Plaintiffs’ agreed form of remedy. The Court should enforce the parties’ contractual agreement and compel Plaintiffs to arbitrate this dispute.

3. CIETAC, The Forum Designated For Arbitration By The Agreement, Provides An Adequate Forum For Plaintiffs’ Claims.

“[A]rbitration is a matter of contract.” *Rent-A-Center West, Inc. v. Jackson*, 561 U.S. 63, 67 (2010). “In line with th[at] principle[], courts must place arbitration agreements on equal footing with other contracts, and enforce them according to their terms.” *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 339 (2011). Plaintiffs’ request that this Court refuse to enforce the arbitration clause is nothing more than a blatant attempt to circumvent an undisputedly valid

contract simply because they no longer prefer one of its terms. The Court should not permit such gamesmanship.

In entering into the Agreement, Plaintiffs affirmatively chose CIETAC as the forum for resolution of its disputes. They do not dispute that they understood CIETAC processes and procedures, or that those processes and procedures are clearly established and publicly available. Plaintiffs have full and complete access to CIETAC. If they cannot attend a CIETAC proceeding in person, they may attend via a personal representative, (*see* Br. in Supp. of Mot. to Compel (Doc. 19-1), at 23-24)—another point that Plaintiffs do not contest, (*see* Opp’n Br. (Doc. 23), at 22). CIETAC rules also allow parties to stipulate or request that the arbitration proceeding either be resolved on the papers without an oral hearing, *see* CIETAC Arb. R. art. 35(2), or that an online hearing be conducted so that one or more parties may attend via videoconference, *see* CIETAC Online Arb. R. art. 33 (“Where an oral hearing is to be held, it shall be conducted by means of online oral hearings such as video conferencing or other electronic or computer communication forms.”). Such procedures allow Plaintiffs to participate meaningfully in the form of dispute resolution to which they contractually agreed and establish that Plaintiffs’ performance of their arbitration obligations is not “impractical.” CIETAC procedures provide ways in which Plaintiffs may participate other than by their in-person presence in China. While that may entail a proceeding and forum that Plaintiffs no longer prefer, it is not a basis for the Court to refuse to enforce a contract. Indeed, federal courts have granted motions to compel arbitration before CIETAC and have enforced its arbitral awards.<sup>3</sup>

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<sup>3</sup> The fact that multiple federal courts have granted motions to compel arbitration before CIETAC and have enforced its arbitral awards reinforces the fairness and adequacy of that tribunal to hear Plaintiffs’ claims. *See, e.g., Baoding Tianwei Group Co. v. Pacifcorp*, No. 07-862, 2008 WL 4224828, at \*10-11 (D. Or. Sept. 10, 2008) (enforcing arbitration clause providing for arbitration before CIETAC); *see also Calbex Mineral Ltd. v. ACC Res. Co.*, 90 F. Supp. 3d 442, 465 (W.D. Pa. 2015) (confirming arbitration award rendered by CIETAC because, notwithstanding allegation of error in the proceeding, the defendant failed to show the existence of any prejudice during the CIETAC

Plaintiffs likewise cannot circumvent their duty to arbitrate by claiming unclean hands by Defendants. Were that permitted, every plaintiff who agreed to arbitrate could renege on that promise simply by raising unproven allegations of misconduct against a defendant and arguing that arbitration is now inappropriate because of the alleged wrongful conduct. Contracts cannot be so lightly cast aside, and it would be inappropriate to do so here. As they themselves allege, Humphrey and Yu were sophisticated, “specialized” investigators highly capable of operating in China. (Compl. (Doc. 1) ¶¶ 6-7.) Humphrey is “a leading anti-fraud professional,” who “assist[s] U.S. and European law firms and businesses [to] investigate and address compliance issues pertaining to anti-bribery regulations.” (*Id.* ¶ 6.) Through ChinaWhys, Humphrey and Yu built a career on “FCPA investigations and other internal investigations” in China, (*id.* ¶ 9), with a focus on “exposure and prevention of corruption and fraud,” (*id.* ¶ 8.) Given their own acknowledged sophistication in dealing with multinational companies and matters, there is nothing inequitable in enforcing the arbitration agreement that Humphrey, Yu, and ChinaWhys knowingly agreed to when they executed the Agreement with GSK China. The Court should grant the GSK Defendants’ motion, enforce the valid arbitration provision, and compel Plaintiffs to arbitrate.

**B. The Complaint Does Not Allege Any Plausible Claims Against GSK PLC And GSK LLC.**

1. The Entirety Of Plaintiffs’ Claims Concern Contacts With GSK China, and Plaintiffs Have Not Alleged Any Basis To Impute GSK China’s Contacts To Either GSK PLC Or GSK LLC.

Plaintiffs do not even attempt to respond to Defendants’ statement that all of their claims must be dismissed because they name the wrong corporate entities as defendants and fail to plead any plausible basis on which GSK PLC or GSK LLC might be vicariously liable for the actions

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proceeding); *Animal Sci. Prods., Inc. v. China Minmetals Corp.*, 34 F. Supp. 3d 465, 519-20 (D.N.J. 2014) (suggesting, without deciding, that CIETAC provides a fair and equitable forum for arbitration of claims).

of GSK China employees. Plaintiffs instead argue that the Court should not consider, in connection with analysis of standing under Rule 12(b)(1), declarations submitted by Defendants establishing that the employees who interacted with Plaintiffs did not work for GSK PLC and GSK LLC.<sup>4</sup>

Plaintiffs ignore, however, that their own Complaint establishes this fact, as it identifies, among others, Reilly as the general manager and CEO of GSK China, (*see* Compl. (Doc. 1) ¶ 45), Zhao as a counsel employed by GSK China, (*Id.* ¶ 50), Joon Soon as an employee of GSK Pte Ltd (a Singapore-based GSK subsidiary), (*Id.* ¶ 80), and Leslie Chang as GSK China’s head of business development, (*Id.* ¶ 84). Critically, Plaintiffs fail to plead that they interacted with *any* employees of GSK LLC or GSK PLC; they also fail to plead any basis on which GSK LLC or GSK PLC might be held liable under an agency theory for the actions of the employees of GSK China (and other Asian GSK entities) whom they identify in the Complaint.

Plaintiffs claim in their Opposition that the Complaint plausibly alleges that “the Defendants engaged in the fraudulent conduct through their agents based in China (regardless of which entity technically employed those agents),” (*see* Opp’n Br. (Doc. 23), at 40), but they offer no citation to the Complaint for this conclusory statement, and for good reason. The Complaint contains no agency allegations at all, beyond the single assertion that GSK PLC “had the right to and did exercise control over the actions of” GSK China—a statement that could be made of *any* majority shareholder of a corporate entity. (*See* Compl. ¶ 10.) Mere right of control attributable to stock ownership is insufficient as a matter of law to impute the actions of a subsidiary to its parent. *Thomas v. Siemens AG*, Civ. No. 09-4414, 2010 WL 1711775, at \*5 (E.D. Pa. Apr. 26,

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<sup>4</sup> GSK’s counsel has contacted Westlaw to correct the appellate history for *Davis v. Wells Fargo U.S. Bank Nat’l Ass’n*, No. 14-07014, 2015 WL 3555301 (E.D. Pa. June 8, 2015), which was previously incorrectly reported by Westlaw, stating that the opinion was “affirmed.” Following that communication to Westlaw, the Westlaw history tab now (correctly) indicates that the opinion was “vacated in part and affirmed in part.”

2010) (denying request to amend complaint to assert agency liability against corporate parent: “[Plaintiff] must present enough facts to link each defendant to the fraud. Mere factual and legal relationships between defendants are not enough to impute knowledge of and actual participation in the fraud to a defendant. Otherwise, a plaintiff could implicate a defendant by asserting mere guilt by association.”). Plaintiffs allege no facts to link either GSK PLC or GSK LLC to GSK China relating to the allegations of harm here.

Nor have Plaintiffs pleaded allegations sufficient to establish any plausible basis for alter ego liability against GSK PLC or GSK LLC. *Global Fresh Produce, Inc. v. Epicure Trading, Inc.*, No. 11-01270, 2012 WL 924326, at \*5 (D.N.J. Mar. 16, 2012) (dismissing claims against parent under Rule 12(b)(6), despite allegation of joint employment by parent and subsidiary of officers and employees and sharing of office space, because the Complaint did not “allege that the parent completely dominated the finances, policy, and business practice with respect to the subject transaction to such a degree that the subsidiary has no separate mind, will or existence of its own.” (internal quotation marks omitted)). Plaintiffs cannot simply pretend, through the device of pleading as to one aggregated “GSK,” that the corporate forms of the distinct GSK entities addressed in their Complaint do not exist. *Indianapolis Live Ins. Co. v. Hentz*, No 1:06-CV-2152, 2008 WL 4453223, at \*11 (M.D. Pa. Sept. 30, 2008) (dismissing fraud claims under Rule 12(b)(6): “One serious deficiency with the Complaint is that after identifying AmerUs Group, AmerUs Life, and Indianapolis Life as separate corporate entities, it goes on to group them together as the ‘Insurance Company’ for all of the substantive allegations of the complaint. . . . In a case involving multiple defendants, each defendant is entitled to be apprised of the roles they each played in the alleged scheme, and absent a compelling reason, a plaintiff is not normally entitled to treat multiple corporate defendants as one entity.”).

For the additional reasons set forth in GSK’s opening brief, (*see* Br. in Supp. of Mot. to Compl. (Doc. 19-1), at 27-29)—to which Plaintiffs have not responded—in the absence of well-pleaded alter ego or agency allegations against GSK PLC or GSK LLC, all claims against them must be dismissed under Rule 12(b)(6) for failure to plausibly allege any basis for purported liability.

2. Plaintiffs Have Failed To Establish Jurisdiction Over GSK PLC.

i. *The Court Does Not Have General Jurisdiction Over GSK PLC.*

Plaintiffs do not contest that a corporation is only subject to general jurisdiction where its “affiliations with the state are so continuous and systematic as to render [it] essentially at home in the forum state.” *Goodyear Dunlop Tire Operations S.A. v. Brown*, 564 U.S. 915, 919 (2011) (internal quotation marks omitted). GSK PLC is “at home” neither in Pennsylvania nor in the United States, and thus is not subject to the Court’s general jurisdiction.<sup>5</sup>

Plaintiffs’ argument to the contrary rests entirely on a mischaracterization of materials from the GSK global website. As that website plainly states: GSK PLC’s “global headquarters are in the UK.” (*See* Zach Decl. (Doc. 24-2), Ex. B.) Further, both the Philadelphia, Pennsylvania and Research Triangle Park, North Carolina locations listed on the very excerpt submitted by Plaintiffs show links connecting to the website of “GSK USA”—*not* GSK PLC. Nor is GSK PLC’s general counsel, Dan Troy, based in Philadelphia. As Plaintiffs’ own submissions to this Court demonstrate, he is based in Washington, D.C.; his presence there

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<sup>5</sup> If Plaintiffs’ RICO claims are dismissed, as they should be, the relevant forum for purposes of analysis of GSK PLC’s minimum contacts is Pennsylvania, not the United States as a whole, for a nationwide contacts analysis only applies to claims arising under federal law. *BP Chemicals Ltd. v. Formosa Chemical & Fibre Corp.*, 229 F.3d 254, 258 (3d Cir. 2000) (“Rule 4(k)(2) thus sanctions personal jurisdiction over foreign defendants for claims arising under federal law when the defendant has sufficient contacts with the nation as a whole to justify the imposition of United States’ law but without sufficient contacts to satisfy the due process concerns of the long-arm statute of any particular state.” (internal quotations omitted)).

cannot be used to argue that somehow Philadelphia is GSK PLC's headquarters.<sup>6</sup> (See Zach Decl. (Doc. 24-1), Ex. A.)

In essence, Plaintiffs' entire argument that general jurisdiction exists rests on but two bases: (1) GSK PLC's global ethics and compliance group maintains reporting contacts and an offsite mailbox in Philadelphia, and (2) only with respect to Plaintiffs' RICO counts, GSK PLC's general counsel is based in Washington, D.C. This is nothing like the *Perkins* case, the only case cited by Plaintiffs, in which the defendant company had transferred its entire headquarters to Ohio during the Second World War, where it held board meetings, conducted banking activities, and engaged in "continuous and systematic supervision of the necessarily limited wartime activities of the company." *Perkins v. Benguet Consol. Mining Co.*, 342 U.S. 437, 448 (1952). *Perkins* involved a foreign company's temporary transfer of its corporate headquarters *in toto* to the United States, not its location of a single corporate officer, or an isolated corporate function, in the United States. Neither GSK PLC's maintenance of a compliance reporting address in Philadelphia, nor its basing of its general counsel in Washington D.C., are even remotely similar to *Perkins*. GSK PLC's global headquarters is in the U.K. and it has never conducted commercial operations in the United States. Plaintiffs have neither pleaded nor offered any basis on which the Court could conclude that GSK PLC is "at home" either in Pennsylvania or the United States. (See Ex. 13 to Mot. to Compel (Doc. 19-17) ¶¶ 9-16.)

ii. *The Court Does Not Have Specific Jurisdiction Over GSK PLC.*

Plaintiffs acknowledge in their Opposition Brief that specific jurisdiction over GSK PLC can only arise if GSK PLC's "suit-related conduct" creates "a substantial connection to the

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<sup>6</sup> Along with their Opposition Brief, Plaintiffs have submitted additional evidence that does not appear in the Complaint. Although the Court may consider those materials for purposes of GSK PLC's jurisdictional challenge, the extrinsic evidence may not be considered in connection with the GSK Defendants' motions under Rules 12(b)(6) and (7). See *Pennsylvania ex rel. Zimmerman v. PepsiCo.*, 836 F.2d 173, 181 (3d Cir. 1988) ("[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." (quoting *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1107 (7th Cir. 1984))).

forum.” *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014). The actual contacts with the United States alleged by Plaintiffs, (*see* Opp’n Br. (Doc. 23), at 27-28), come nowhere close to that standard. Specifically:

- Plaintiffs nowhere allege that conduct by GSK PLC was the subject of the 2012 settlement with U.S. regulators. In fact, plaintiffs allege only that GSK LLC was involved in that settlement.
- The fact that whistleblowers may have threatened GSK PLC with disclosure to the DOJ or the SEC, or that whistleblower emails may have been received by GSK PLC employees in the United States, is irrelevant to the specific jurisdiction analysis, which must focus on the actions of GSK PLC, not third parties. *Walden*, 134 S. Ct. at 1122 (“[T]he relationship must arise out of contacts that the defendant himself creates with the forum State.... We have consistently rejected attempts to satisfy the defendant-focused minimum contacts inquiry by demonstrating contacts between the plaintiff (or third parties) and the forum State.”) (citations omitted).
- The Complaint nowhere alleges any conduct by GSK’s general counsel,<sup>7</sup> and thus the Court should ignore Plaintiffs’ attempt to insert him into the specific jurisdiction analysis. (*See* Opp’n Br. (Doc. 23), at 27.) The article cited by Plaintiffs, (*see* Zach. Decl. (Doc. 24-1), Ex. A), states only that Mr. Troy was involved in managing an internal investigation subsequent to the disclosure of the investigation by China’s Ministry of Public Security, which occurred, according to the allegations in the Complaint, only after GSK China retained Plaintiffs. His alleged conduct thus would have no relevance to the jurisdictional inquiry in any event.
- Plaintiffs do not claim that Humphrey’s travel to the United States had any connection to the work he was engaged to perform by GSK China. Nor do Plaintiffs allege—because they cannot—that any employee of GSK PLC ever contacted Humphrey while he was in the United States or anywhere else.
- Plaintiffs do not allege that GSK PLC purposefully directed any public statements to the United States, nor do they plead that any public statements made by GSK PLC had any effect outside of China. The only statements cited by Plaintiffs were general press releases issued by GSK PLC from the U.K. in response to events in China.
- GSK PLC’s 2016 settlement with the SEC related only to the effectiveness of GSK PLC’s controls in China, not the United States. None of the factual findings recited by Plaintiffs in their Opposition relate to any activities of GSK PLC that were purposefully directed towards the United States – all of the underlying misconduct was performed by GSK China, in China. Nor can GSK PLC’s subsequent

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<sup>7</sup> Plaintiffs reference ¶ 54 of the Complaint, but this refers only to the receipt by GSK’s general counsel of whistleblower complaints. As discussed immediately above, this is irrelevant to the specific jurisdiction analysis.

remediation reporting to the SEC be construed as suit-related conduct that gives rise to Plaintiffs' claims.

In short, Plaintiffs nowhere allege the sort of suit-related conduct creating a substantial connection with either Pennsylvania or the United States that could establish specific jurisdiction over GSK PLC.<sup>8</sup>

3. The Court Should Dismiss Plaintiffs' RICO Claims Under Federal Rule Of Civil Procedure 12(B)(6) Because They Have Failed To Plead The Elements Of Recovery Under The Statute.

i. Plaintiffs Have Not Alleged A Domestic Injury.

In their Opposition Brief, Plaintiffs do not cite a single case supporting the proposition that a foreign corporation, like plaintiff ChinaWhys, can claim to have suffered a domestic injury merely by alleging that it lost customers in the United States. Nor do they cite any cases supporting the idea that an injury is "domestic" merely because it arises from a purported RICO scheme allegedly intended to affect third parties in the United States, such as U.S. regulators or U.S. physicians, who are unrelated to and never interacted with the plaintiffs or even knew of their existence.

In *City of Almaty, Khazakhstan v. Ablyazov*, the court dismissed RICO claims for failure to allege a domestic injury, given that the plaintiffs "got poorer in Kazakhstan[.]" where their assets were located, and failed to allege any work, travel or business in the United States that was related to the misappropriations alleged by plaintiffs as the basis of their RICO claims. *City of Almaty, Khazakhstan v. Ablyazov*, 15-CV-5345, 2016 WL 7756629, at \*7-9 (S.D.N.Y. Dec. 23, 2016) ("[T]he appropriate subject of the inquiry required by *RJR Nabisco* is . . . the location

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<sup>8</sup> In a footnote, Plaintiffs seek discovery concerning "the extent to which GSK PLC acted within the United States with respect to the claims." (*See* Opp'n Br. (Doc. 23), at 27 n.10). This request has no reasonable basis. A court should not allow jurisdictional discovery to serve as "a fishing expedition based only upon bare allegations, under the guise of jurisdictional discovery." *Eurofins Pharma U.S. Holdings v. BioAlliance Pharma SA*, 623 F.3d 147, 157 (3d Cir. 2010). Given Plaintiffs' failure to allege contacts between GSK PLC and the United States, this Court should exercise its discretion to deny any such discovery.

where the injury itself arose.”). In *Elsevier v. Grossman*, the court considered the defendant’s below-market sales of academic journals in Brazil, concluded that any resulting market distortions and accompanying RICO injuries occurred in Brazil, and dismissed the RICO claim for failure to allege a domestic injury. *Elsevier v. Grossman*, 12 Civ. 5121, 2016 WL 7077109 at \*13-14 (S.D.N.Y. Aug. 4, 2016).

*Akishev v. Kapustin and Tatung Company, Ltd. v. Shu Tze Hsu*, the only two cases cited by Plaintiffs in which domestic injuries were actually found, both involved claims in which the plaintiffs’ interactions with the defendants—and the foci of the underlying RICO schemes—occurred in the United States. *Akishev v. Kapustin*, No. 13-7152, 2016 WL 7165714, at \*7 (D.N.J. Dec. 8, 2016) (“The key to this case is that plaintiffs suffered their injuries the moment they clicked the computer mouse – on a United States-based website – and ordered and paid for a car whose condition was materially misrepresented or did not even exist at all.”); *Tatung Co., v. Shu Tze Hsu*, SA CV 13-1743, 2016 WL 6683201, at \*8 (C.D. Cal. Nov. 14, 2016) (“[D]efendants specifically targeted their conduct at California with the aim of thwarting [plaintiff’s] rights in California.”). That is not the case here. Plaintiffs do not allege that they were engaged to perform any work in the United States, nor do they allege a connection between their United States customers and the work in China that Plaintiffs actually performed.

Further, Plaintiffs’ spurious allegation that GSK purportedly hoped to reap benefits in the United States (by influencing U.S. regulators) is not sufficient to establish that Plaintiffs’ injury was domestic, for the same allegation could be made in any RICO claim against any U.S. defendant, and the *RJR Nabisco* inquiry necessarily focuses on the nature of the *plaintiff’s* injury. *RJR Nabisco v. European Cmty.*, 136 S. Ct. 2090, 2106 (2016) (“A private RICO plaintiff . . . must allege and prove a domestic injury to its business or property.”). A number of cases have

considered, and rejected, the argument that a defendant's receipt of benefits in the United States renders an injury domestic. For example, Plaintiffs offer no answer to *Exceed Industries LLC v. Younis*, No. 15 Civ 14, 2016 WL 6599949 (N.D. Ill. Nov 8, 2016), in which the court considered a RICO scheme allegedly involving kickbacks extracted by the defendants from the plaintiff's suppliers (including suppliers in the United States), whose proceeds were used to fund U.S. real estate purchases. Following *RJR Nabisco*, the *Exceed Industries* court properly focused its analysis on the location of the plaintiff's injury and dismissed for failure to allege a domestic injury. *Id.* at \*3 (“[T]he fact that a large number of Plaintiff’s suppliers have offices in the United States does not speak to where the injury was felt by the Plaintiffs themselves. . . .”). In *City of Almaty*, the court similarly rejected the argument that the defendants’ investment of RICO proceeds in the United States rendered the plaintiffs’ injuries “domestic.” *City of Almaty*, 2016 WL 7756629, at \*9 (“The after-the-fact concealment in the U.S. of funds stolen entirely abroad does not constitute a basis for concluding that the Kazakh entities have alleged injury suffered in the U.S.”).

Here, Plaintiffs claim that they were misled in China, for the purpose of inducing them to perform work in China, under a contract executed in China and governed by Chinese law, causing them to be arrested in China and to suffer the destruction of their business, a Chinese consulting company. Plaintiffs have offered absolutely no support for their claim that their injuries should be considered “domestic” simply because they claim to have U.S. customers who were unrelated to the work they performed for GSK China. Under *RJR Nabisco*, their RICO claims must be dismissed.

ii. *Plaintiffs Fail To Allege That Their Injuries Were Proximately Caused By Defendants.*

Plaintiffs do not contest that they must allege that their injuries were proximately caused by Defendants. Their reliance on *In re Avandia Marketing Sales Practices & Product Liability Litigation*, 804 F.3d 633 (3d Cir. 2015), *cert. denied sub nom. GlaxoSmithKline LLC v. Allied Serv. Div. Welfare Fund*, 136 S. Ct. 2409 (2016), to argue that they have satisfied this pleading burden is misplaced.

In *Avandia*, the U.S. Court of Appeals for the Third Circuit noted that the Supreme Court’s decision in *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992), outlined three distinct reasons for requiring a proximate relationship between injuries and alleged conduct in RICO cases, the first of which it described as: “directness of injury: indirect injuries make it difficult to ascertain the amount of a plaintiff’s damages attributable to the violation, as distinct from other, independent factors.” *Id.* at 642. The *Avandia* court identified this as a separate concern under *Holmes* from the “derivative injury” issue on which Plaintiffs focus in their Opposition. *Id.* (identifying “likelihood of vindication” by “directly injured victims” as third distinct justification for *Holmes* decision). Crucially, in *Avandia*, “[t]he conduct that allegedly caused plaintiffs’ injuries [was] the same conduct forming the basis of the RICO scheme alleged in the complaint—the misrepresentation of the heart-related risks of taking Avandia[.]” *Id.* at 644. Accordingly, *Avandia* did not present the problem of untangling multiple, independent causes of the plaintiffs’ damages.

Notably, Plaintiffs nowhere allege in their Complaint that anyone from any GSK entity ever asked them to violate Chinese privacy (or other) laws. In fact, the Agreement required Plaintiffs’ “compliance with the highest ethical standards and all anti-corruption laws applicable in the countries in which GSK ... conducts business,” (*See* Ex. 1 to Mot. to Compel (Doc. 19-5),

at 12), and Plaintiffs do not contest the validity of that provision. China's subsequent punishment of Plaintiffs for their violations of Chinese law thus cannot be considered the proximate result of Plaintiffs' engagement by GSK China to investigate the GSK China employee, even accepting Plaintiffs' allegation (which is disputed) that the ultimate objective of that investigation was improper. Here, the direct cause of Plaintiffs' injuries was the conduct of the Chinese government, an independent actor in this case, over whom GSK had (and has) no control, *not* the conduct of the GSK Defendants alleged in the Complaint.

In short, Plaintiffs' claim falls squarely within one of the fundamental concerns identified by the United States Supreme Court in *Holmes*, as it is impossible to determine what injuries, if any, are attributable to GSK, as opposed to independent factors traceable to the Chinese government's subsequent punishment of Plaintiffs for their own violations of Chinese law. For this reason alone, Plaintiffs' RICO claim must be dismissed.

iii. *Plaintiffs Fail To Allege A RICO Pattern.*

Plaintiffs have alleged as a basis for their RICO claim the existence of: (1) a 2012 settlement agreement between GSK LLC and the United States Department of Justice, (2) a 2014 GSK China settlement with Chinese authorities, and (3) a 2016 GSK PLC settlement with the United States Securities and Exchange Commission. Plaintiffs' only claim in their Complaint, however, is to have been involved in and injured by conduct that occurred in China. They offer nothing more than a conclusory allegation that their injury was part of a larger pattern, despite the fact that the alleged conduct involving Plaintiff was separated in time, place, participants, subject matter and alleged methods of commission from the other elements of their alleged RICO scheme. This is insufficient and does not raise a "reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

Plaintiffs' opposition makes no effort to address law cited by Defendants in the Motion reflecting that: (1) an allegation that one scheme was intended to cover up another scheme is not "sufficient to make two conspiracies part of the same pattern of racketeering," *The Knit With v. Knitting Fever, Inc.*, 625 F. App'x 27, 38 (3d Cir. 2015); and (2) an alleged common corporate purpose, such as maximizing sales, "is not an allegation of a common plan," *Bonavitacola Elec. Contractor, Inc. v. Boro Developers, Inc.*, 87 F. App'x 227, 232 (3d Cir. 2003).

In addition, Plaintiffs make neither an allegation of any threat of an ongoing, open-ended RICO scheme associated with the historical U.S. and Chinese settlements cited by Plaintiffs nor any claims concerning their own involvement beyond a three month period in 2013. As explained in Defendants' opening brief, (*see* Br. in Supp. of Mot. to Compel (Doc. 19-1), at 34), Plaintiffs' claims thus separately fail RICO's continuity requirement. *H.J. Inc. v. Northwestern Bell Tel. Co.*, 492 U.S. 229, 240 (1989) (predicate acts alleged only over a short period of time and not threatening future criminal conduct do not satisfy RICO's continuity requirement).

iv. *Plaintiffs Have Not Alleged An Agreement By GSK LLC Or GSK PLC.*

Without citation to or evidence in the Complaint, Plaintiffs claim that "the Complaint alleges numerous facts relating to Defendants' agreement to engage in the bribery and promotion scheme" and that "Defendants actively participated in the suppression of the whistleblower's allegations." (*See* Opp'n Br. (Doc. 23), at 34 & n.12.) In addition to the baseless nature of these statements, the Complaint does not contain alter ego or agency allegations against either GSK defendant. *See supra* Part II.B.1. The Complaint's bare assertion that "the corporate defendants conspired with, *inter alia*, Mark Reilly and others to promote the red herring investigation of Vivian Shi," (*see* Compl. (Doc. 1) ¶ 140), is insufficient. *The Knit With*, 625 F. App'x at 35-36 ("Plaintiff must allege facts to show that each Defendant objectively manifested an agreement to

participate, directly or indirectly, in the affairs of a RICO enterprise through the commission of two or more predicate acts. Bare allegations of conspiracy described in general terms may be dismissed.”), *cert. denied*, 136 S. Ct. 1662 (2016). Again, that is insufficient under *Twombly* and *Iqbal*.

4. The Court Should Dismiss Plaintiffs’ State Law Claims Both For Lack Of Subject Matter Jurisdiction Under Federal Rule Of Civil Procedure 12(B)(1) And For Failure To State A Claim Under Federal Rule Of Civil Procedure 12(B)(6).
  - i. Once The RICO Claims Are Dismissed, Plaintiffs Cannot Establish Diversity Jurisdiction Over Their State Law Claims.

With regard to the GSK Defendants’ jurisdictional argument, Plaintiffs not only fail to plead Yu’s domicile, they do not even attempt to argue in their Opposition Brief that she is domiciled in the United States. It is the Plaintiffs’ burden to plead the basis for diversity jurisdiction. Having failed to do so, they cannot ask this Court to exercise such jurisdiction. *See Pa. House, Inc. v. Barrett*, 760 F. Supp. 439, 449 (M.D. Pa. 1991) (dismissing under Rule 12(b)(1) for failure to allege diversity of citizenship: “The plaintiff bears the burden of proving that diversity of citizenship exists on the date that the complaint is filed . . . . Because Pennsylvania House fails to allege [defendant] Cruikshank’s domicile, its complaint fails to establish diversity.”)

Further, if Plaintiffs’ RICO claims are dismissed, as they should be, this Court will have no basis on which to exercise supplemental jurisdiction, and Plaintiffs’ remaining claims must then be dismissed in their entirety for lack of subject matter jurisdiction.

ii. *Plaintiffs Have Failed To Plead Claims For Civil Fraud, Civil Conspiracy, And Intentional And Negligent Infliction Of Emotional Distress Against The GSK Defendants.*

(1) *Plaintiffs' Fraud Claim Fails For Lack Of Any Misrepresentation By GSK PLC Or GSK LLC.*

Plaintiffs' argument that, because they may commence suit against whomever they please, it is no defense to suggest that the "wrong defendants once again were named," (*see* Opp'n Br. (Doc. 23), at 38), ignores that the naming of a wrong party is a fundamental and fatal defect in their Complaint. To be sure, Plaintiffs have sued the wrong defendants. (*See* Br. in Supp. of Mot. to Compel (Doc. 19-1), at 35.) Their pleading fails because they have not—and cannot—identify any representation made by GSK PLC and GSK LLC through which they were defrauded. *See Kuehner v. Parsons*, 527 A.2d 627, 629 (Pa. Commw. Ct. 1987) (holding that fraud requires reliance on "a misrepresentation of material fact" made by the defendant).

Plaintiffs' fraud claim is governed by Federal Rule of Civil Procedure 9(b), which requires them to identify, at a minimum, the content and "the speaker of allegedly fraudulent statements." *Klein v. Gen. Nutrition Cos.*, 186 F.3d 338, 345 (3d Cir. 1999). The Complaint contains no specific fraudulent representation, nor does it identify the content or speaker of any alleged fraudulent representation by either of the GSK Defendants. Moreover, Plaintiffs have made no attempt to impute the alleged conduct by GSK China personnel to either of the GSK Defendants. *See Frank Sexton Enters. v. Societe de Diffusion Internationale Argo-Alimentaire (Sodiaal)*, No. 97-7104, 1999 WL 636668, at \*3 (E.D. Pa. Aug. 20, 1999) (holding that one corporation's activities may be imputed to another only if the plaintiff establishes an agency or alter ego relationship between the two).

(2) *Plaintiffs Have Failed To Plead The Malice Element Of Their Civil Conspiracy Claim.*

Plaintiffs suggestion that Defendants' motion "rests on a fundamental misreading of the law" in stating that malice (i.e., the desire or intent to injury) must be pled and proven in addition to the other elements of a civil conspiracy tort, (*see* Opp'n Br. (Doc. 23), at 40), has no basis. As the Pennsylvania Supreme Court has explained: "***Proof of malice, i.e., an intent to injure, is essential in proof of a conspiracy.***" *Skipworth ex rel. Williams v. Lead Indus. Ass'n*, 690 A.2d 169, 174 (Pa. 1997) (emphasis added). Pleading malice requires the plaintiff to allege that "the conspirators act[ed] with the sole purpose of injuring the plaintiff." *Sarpolis v. Tereshko*, 625 F. App'x 594, 601 (3d Cir. 2016) (citing *Thompson Coal Co. v. Pike Coal Co.*, 412 A.2d 466, 472 (Pa. 1979)). No such allegation appears in the Complaint. Plaintiffs claim to have satisfied that obligation by suggesting simply that the GSK Defendants committed an unlawful act, (*see* Opp'n Br. (Doc. 23), at 41), but they cannot circumvent the clear requirement to plead malice (i.e., the specific desire to injure the plaintiff) separately from the other elements of a conspiracy claim. Further, absent alter ego or agency allegations, they cannot impute any alleged misconduct by GSK China to the GSK Defendants. *See Watson v. Sec'y Pa. Dep't of Corr*, 436 F. App'x 131, 137 (3d Cir. 2011) (affirming dismissal of a civil conspiracy claim because the plaintiff alleged the existence of a conspiracy in a conclusory manner but failed to identify any actual agreement among the defendants).

iii. *Plaintiffs Have Not Pled That They Suffered Any Emotional Distress At The Hands Of The GSK Defendants.*

Plaintiffs mischaracterize the GSK Defendants' statement that the acts of Chinese authorities break a "causal link between Defendants' conduct and Plaintiffs' suffering." (*See* Opp'n Br. (Doc. 23), at 42.) The pertinent question is not whether the acts of Chinese authorities constitute a superseding cause, but whether Plaintiffs' harm was attributable in the first place to

any conduct by GSK LLC or GSK PLC. *See Salerno v. Phila. Newspapers, Inc.*, 546 A.2d 1168, 1173 (Pa. Super. Ct. 1988) (stating that a plaintiff must plead that the defendant's conduct had a "direct emotional impact upon the plaintiff"). There is no such link here. If the Complaint alleges any link between the Plaintiffs' injuries and a GSK entity (and the GSK Defendants dispute that it does), it ties Plaintiffs to the GSK China officials with whom Plaintiffs interacted. Those actions cannot be imputed to GSK PLC or GSK LLC on Plaintiffs' say-so alone. *See Frank Sexton Enters.*, 1999 WL 636668, at \*3 (noting that an alter ego or agency relationship is required to impute corporate contacts).

5. Plaintiffs' State Law Claims Fail For The Additional Reason That They Are Barred By Pennsylvania's Two-Year Statute Of Limitations.

Plaintiffs acknowledge that their state tort claims are governed by Pennsylvania's two-year statute of limitations, *see* 42 Pa. C.S.C. § 5524, but they suggest that, because "the Complaint does not identify when Plaintiffs learned that they had been defrauded," the Court cannot apply the limitations period as a defense at the pleading stage. (*See* Opp'n Br. (Doc. 23), at 43.) The Court should reject their effort, however artful, to plead around a limitations defense.

Although Plaintiffs dispute the choice of the applicable date, they purposefully refuse to commit to any particular date as the applicable limitations trigger date. They claim that they could not have known of the GSK Defendants' alleged misrepresentations until September 19, 2014, the date of issuance of a public statement by GSK regarding alleged bribery conduct by GSK China, such that the discovery rule rendered their claims timely if filed within two years following that date. (*See* Opp'n Br. (Doc. 23), at 43-44.)

Plaintiff's own allegations in their Complaint, however, demonstrate that they knew of the alleged misrepresentations well before they sustained any injury. Specifically, Plaintiffs allege that by June 2013, Humphrey became "concerned that GSK was seeking to obstruct ...

investigation by Chinese authorities.” (*See* Compl. (Doc. 1) ¶ 83.) Plaintiffs also allege that, when Chinese police raided ChinaWhys’s Shanghai office on July 10, 2013, they informed Humphrey that “[t]his is related to GSK.” (*Id.* ¶ 91.) Plaintiffs have thus alleged that by July 10, 2013, they had not only become “concerned” about GSK’s conduct, but had suffered injuries they were informed “related to GSK.” Therefore, Plaintiffs’ claims accrued at the latest on July 10, 2013. *See Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384 n.1 (3d Cir. 1994) (holding that a claim accrues when the plaintiff becomes aware of the injury). Plaintiffs cannot now claim that they did not know of the existence of their tort claims prior to the public apology on September 19, 2014. *See Bohus v. Beloff*, 950 F.2d 919, 926 (3d Cir. 1991) (holding that, under Pennsylvania law, the discovery rule only tolls the limitations period until the plaintiff “knew or should have known” of the existence of their claims).

Applying Pennsylvania’s two-year limitations period applicable to fraud claims yields a filing deadline of July 10, 2015 for their state law claims. They did not commence this litigation until November 15, 2016, making their action time-barred.

Humphrey and Yu claim that the limitations period should have been tolled during their trial and incarceration. (*See* Opp’n Br. (Doc. 23), at 45.) However, the U.S. Court of Appeals for the Third Circuit has recognized that equitable tolling should not apply if the plaintiff, “acting with reasonable diligence, could have filed on time notwithstanding the extraordinary circumstances.” *Brown v. Shannon*, 322 F.3d 768, 773 (3d Cir. 2003) (quoting *Valverde v. Stinson*, 224 F.3d 129, 134 (2d Cir. 2000)). Plaintiffs allege that they were released on June 9, 2015, (*see* Compl. (Doc. 1) ¶ 105), well in advance of the July 10, 2015 deadline by which they should have filed their state law claims, and the Complaint contains no facts alleging that they were precluded from making a timely filing following their release. Accordingly, on the face of

the Complaint, Plaintiffs' claims are time-barred. *See Oshiver*, 38 F.3d at 1384 n.1 (holding that a court may dismiss a complaint as time-barred when "the complaint facially shows noncompliance with the limitations period and the affirmative defense clearly appears on the face of the pleading").

**C. GSK China Is An Indispensable Party, And The Complaint Should Be Dismissed Under Federal Rule Of Civil Procedure 12(B)(7) For Failure To Join GSK China As A Party.**

Plaintiffs' argument that GSK China is not an indispensable party turns on their assertion (Opp'n Br. (Doc. 23), at 46) that the Complaint plausibly alleges that the Defendants, GSK PLC and GSK LLC, acted "through their agents in China." As discussed above, however, the Complaint contains no allegations of agency liability on the part of GSK PLC or GSK LLC. Nor does the Complaint allege that Plaintiffs interacted with any employees of GSK PLC or GSK LLC; instead Plaintiffs allege only interactions with GSK China.

Given this backdrop, the conclusion that GSK PLC and GSK LLC are being sued here solely in connection with the conduct of GSK China is inescapable. GSK China was the only point of contact with Plaintiffs, and GSK China was the only GSK entity to enter into the Agreement with Plaintiffs that defined the work they now claim gave rise to their injuries. GSK China has a compelling interest in the adjudication of any claims arising out of the relationship with Plaintiffs arising from that contract, and Plaintiffs have offered no response to the well-established case law which holds that "when a defendant is sued solely in connection with its subsidiary's conduct, the subsidiary is a necessary and indispensable party." *Carl Schroeter v. Crawford & Co.*, No. 09-946, 2009 WL 1408100, at \*4 (E.D. Pa. May 19, 2009) (collecting cases). None of the authorities cited by Plaintiffs address the parent-subsidiary issues that are presented here.

Nor do Plaintiffs have any response to the opinion of the U.S. Court of Appeals for the Third Circuit in *Jurimex*, affirming the district court's dismissal for failure to join an indispensable party and rejection of an argument strikingly similar to the one offered by Plaintiffs here:

[Defendant parent] Case filed a motion to dismiss pursuant to 12(b)(1) and 12(b)(7), arguing that its foreign subsidiaries were necessary and indispensable parties under Rule 19 and addition of those parties would destroy diversity jurisdiction. The District Court agreed and granted the motion. [Plaintiff] Jurimex argued that it was trying to hold Case liable, not as merely the parent of the subsidiaries, but rather because the subsidiaries were acting as agents of Case. However, this theory could not be found anywhere in the original complaint (indeed, there was no mention of a subsidiary). The District Court properly applied a Rule 19 analysis and dismissed the complaint. The District Court also properly denied discovery on the agency theory at that time because there was nothing in the complaint to which the theory could relate.

*Jurimex Kommerz Transit GMBH v. Case Corp.*, 65 F. App'x 803, 804 (3d Cir. 2003). Like the *Jurimex* plaintiffs, Plaintiffs cannot try to evade the fact that GSK China is indispensable through the artificial device of excising it from their Complaint.

### **III. CONCLUSION**

Plaintiffs agreed to arbitration. They negotiated and executed the Consultancy Agreement and have not challenged its validity. They allege harm related to services they performed pursuant to the same Agreement. The Court should therefore compel arbitration before CIETAC and stay this matter pending conclusion of arbitration proceedings.

Absent such an order, the Court should dismiss Plaintiffs' claims against GSK PLC for lack of jurisdiction, as that entity does not have sufficient contacts to support the exercise of either general or specific jurisdiction under either *Goodyear Dunlop Tire Operations S.A. v. Brown*, 564 U.S. 915 (2011), or *Walden v. Fiore*, 134 S. Ct. 1115 (2014). The claims against both GSK PLC and GSK LLC should additionally be dismissed for failure to state any plausible

claim for relief and for failure to join the only party with whom Plaintiffs actually interacted: GSK China. Accordingly, the GSK Defendants request that, if the Court denies the motion to compel arbitration, it simultaneously dismiss the entirety of Plaintiffs' Complaint with prejudice.

Dated: March 31, 2017

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on March 31, 2017, I caused a copy of the foregoing Motion to Compel Arbitration or, in the Alternative, Motion to Dismiss the Complaint, along with the accompanying Memorandum of Law and exhibits thereto, to be served on the following individuals via the means specified below:

**Via the Court's CM/ECF System:**

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